Medtronic

5388

Dual Chamber Temporary Pacemaker

Technical Manual

! USA **Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician.

CE 0123

MODEL 5388

Technical Manual

Dual Chamber Temporary Pacemaker

Symbols

Explanation of symbols

	Consult instructions for use
	Type CF Equipment
	Conformité **E**uropéenne (European Conformity) This symbol means that the device fully complies with European Directive 93/42/EEC .
	Do not dispose of this product in the unsorted municipal waste stream. Dispose of this product according to local regulations. See http://recycling.medtronic.com for instructions on proper disposal of this product.
! USA	For US audiences only

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General Description

The Medtronic® Model 5388 is a battery-powered, temporary, dual chamber pacemaker designed primarily for temporary antibradycardia pacing therapy. The device provides eight selectable modes of pacing therapy: DDD, DVI, DDI, DOO, VOO, VVI, AOO, and AAI. High-rate, burst pacing therapy up to 800 min^{-1} (reciprocal minutes), for atrial tachyarrhythmias, is available in the asynchronous mode.[1]

The device is typically connected to temporary transvenous, epicardial or myocardial pacing leads, in a bipolar configuration, using patient cables (Medtronic Models 5433A and 5433V) or surgical cables (Medtronic Model 5832 or 5832S).

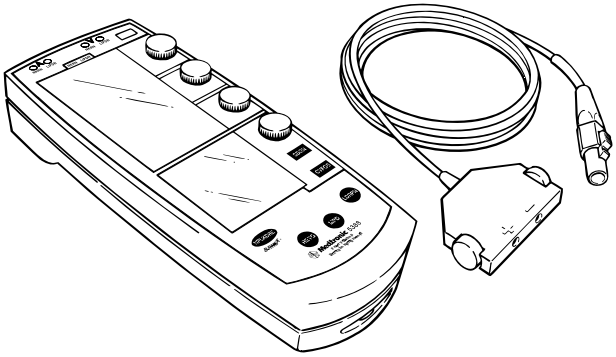

Figure 1-1. The Medtronic Model 5388 Dual Chamber Temporary Pacemaker and the Model 5433A or 5433V Patient Cable.

The device operates using a 9-volt alkaline or lithium battery, installed in the battery drawer at the lower right side of the device.

Note: The Model 5388 is a constant current device. When it emits a pulse, the current output is maintained at a constant value. This value is set by the output control and does not vary.

[1] For atrial use only.

Safety Features

The Medtronic Model 5388 is designed to be reliable, easy to operate, and comfortable to hold. Safety features of the Model 5388 include:

- Cables with no exposed electrical connections;
- Self-test function;
- Low Battery indicator;
- Lock feature to prevent accidental change of parameters;
- Safe, two-step operation to turn the device off;
- Runaway rate protection;
- Protection from defibrillation shock;
- Continuous operation during battery replacement (see page 103);
- Reversible battery polarity;
- Electrostatic protection;
- Minimized susceptibility to electromagnetic and magnetic interference; and
- Rubber seals to cover the connector pin receptacles.

Package Contents

See the enclosed card for a detailed list of package contents. Check the package prior to use. Damaged packages should be returned to Medtronic (see back cover for address).

Registration Card

Please complete the registration card and return it to Medtronic. Consult the back cover of this manual for the address.

Intended Use

The Medtronic Model 5388 temporary pacemaker is intended to be used in conjunction with a cardiac pacing lead system for temporary single or dual chamber pacing in a clinical environment by trained personnel. The Model 5388 can be used where short-term demand (synchronous) or asynchronous pacing is indicated for therapeutic, prophylactic or diagnostic purposes.

Specific indications for temporary cardiac pacing include, but are not limited to, the following:

- Complete heart block;
- Sinus bradycardia;
- Sick sinus syndrome;
- Bradycardia with congestive heart failure;
- Atrial and/or ventricular arrhythmias;
- Cardiac arrest;
- Support, management, and evaluation of a patient prior to permanent pacemaker implantation;
- Support during permanent pacemaker replacement;
- Cardiac complications during invasive or surgical procedures;
- Support following cardiac surgery;
- Acute myocardial infarction complicated by heart block; and
- High-rate burst pacing for treatment of atrial tachyarrhythmias.

The Model 5388 can be used to determine sensing thresholds of temporary and permanently implanted lead systems. When implanting a permanent pacemaker, however, Medtronic recommends the use of a Medtronic Pacing System Analyzer.

Contraindications

There are no known contraindications to the use of temporary pacing as a means to control the heart rate. The patient's age and medical condition, however, may dictate the type of temporary pacemaker and lead system used by the physician.

Atrial Sensing

Pacing modes which allow sensing in the atrium to trigger a ventricular response are contraindicated in the presence of rapid atrial arrhythmias such as atrial fibrillation or atrial flutter.

Atrial Pacing

Atrial pacing is ineffective in the presence of atrial fibrillation or flutter.

Single chamber atrial pacing is contraindicated in the presence of AV conduction disorders.

Asynchronous Pacing

Asynchronous pacing is contraindicated in the presence of intrinsic cardiac rhythms.

Atrial High-Rate Burst Pacing Therapy

Atrial high-rate burst pacing therapy is intended for use in the **atrium only.** High-rate burst pacing in the ventricle may result in life-threatening arrhythmias.

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Warnings

Defibrillation/Cardioversion

Defibrillation discharges up to 360 watt-seconds have not affected the Model 5388 in laboratory tests. However, for maximum safety, it is recommended that paddles be placed at least 15 cm (6 inches) away from the Model 5388 or the lead system.

Whenever possible, for the safety of the patient, disconnect the pacemaker from the lead system before defibrillating or cardioverting. A relatively low resistance pathway exists between the positive (+) and negative (–) electrodes of the implanted lead system. During defibrillation a large current could flow across this pathway, causing myocardial damage.

Line-powered Equipment

An implanted lead or lead with extension cable constitutes a direct, low-resistance current pathway to the myocardium. Due to the danger of tachyarrhythmias resulting from alternating current leakage, extreme caution must be taken to properly ground all line-powered equipment used on or in the vicinity of the patient.

Electrosurgical Units (Cautery)

Electrosurgical units can cause tachyarrhythmias by inducing current on the leads, and thus should never be used within 15 cm (6 inches) of the pacemaker/lead system.

Electromagnetic Interference (EMI)

Pacemakers operating in the demand mode respond to intracardiac potentials with magnitudes of a few millivolts. This level of sensitivity makes the pacemaker inherently sensitive to some external fields. In the presence of excessive levels of interference, the Model 5388 may inhibit completely or revert to asynchronous operation, pacing at the rate set by the **RATE** dial.

It is recommended that the device be set to an asynchronous mode at a rate higher than the patient's intrinsic rate when operated in the presence of strong electromagnetic interference (EMI).

Sources of excessively strong EMI which may temporarily affect the operation of the Model 5388 include:

- Electrosurgical equipment;
- Diathermy equipment;
- Some medical telemetry equipment [when operated within one meter (about three feet) of the pacemaker];
- Communication transmitters such as cellular phones, “walkie talkies”, and transmitters in emergency transport vehicles; and
- Magnetic Resonance Imaging (MRI) equipment.

Atrial High-Rate Burst Pacing Therapy

Use of high rates in the atrium could result in high-rate conduction to the ventricle. Defibrillation equipment should be on standby, immediately available during atrial high-rate burst pacing therapy.

There is no ventricular back-up pacing during delivery of atrial high-rate burst pacing therapy.

Connecting the Lead System

The patient cable should be connected to the temporary pacemaker before the lead(s) is connected to the patient cable(s).

To prevent pacing into the vulnerable period of the T-wave, turn the temporary pacemaker ON and turn A and V OUTPUT down to the minimum amplitude before connecting the temporary pacemaker to the patient’s lead system. Determine sensing thresholds (see “Sensing Threshold” on page 82) before turning A and V OUTPUT up to threshold levels.

Handling Implanted Leads

When handling implanted leads (temporary or permanent), the terminal pins or exposed metal must not be touched nor be allowed to contact electrically conductive or wet surfaces.

Precautions

Random Failures

The physician should be aware that operational failure of the Model 5388 temporary pacemaker can occur as the result of battery depletion, mishandling, or random component failure.

Possible operational failures of the Model 5388 can include:

- No output or erratic output;
- No sensing or erratic sensing;
- False indicator light signals;
- Inappropriate variance of rate, output pulse width, or output amplitude;
- Reversion to asynchronous pacing; and
- Loss of control of rate, output, sensitivity or power.

If loss of control of rate, output, sensitivity or power occurs, and it is not due to a low battery, disconnect the device from the patient and return it to Medtronic for service.

Batteries

Use of batteries with different physical dimensions from that of the recommended batteries may result in erratic, or no, pacing output.

Replace the battery for each new patient, and when the low battery indicator appears during device operation (see page 31).

Check the battery status at least twice daily. Replace alkaline batteries at least once every week when the temporary pacemaker is in continuous use or when the low battery indicator is displayed. When replacing the battery, make sure the battery drawer is fully closed and latches in place with an audible click.

Inspect the contacts on the battery for visible signs of contamination prior to use. Use of batteries with contamination on the contacts may result in erratic, or no output.

Failure to ensure that the battery drawer is fully latched may result in a loss of power. Continued device operation is NOT an indication that the battery drawer is properly latched.

Pacing Leads and Cables

Improper connection, displacement or fracture of leads or cables may result in pacemaker system failure. Inspect leads and cables for damage prior to each use.

Pacing System Adjustments

Monitor the patient's ECG and blood pressure and keep defibrillation equipment on standby, immediately available for emergency use during evaluation of stimulation and sensing thresholds, pacemaker and pacing lead connections and adjustments, and atrial high-rate burst pacing therapy.

Bipolar Lead Systems

Bipolar lead systems are recommended because they are less susceptible to electromagnetic interference. Separation between the positive (+) electrode and negative (–) electrode of the same lead system should not exceed 15 mm (0.6 inches). Also, the atrial and ventricular lead systems should be positioned so that the electrodes of one system are a minimum of 4 cm (1.5 inches) from the electrodes of the other system and are at right angles to each other.

Unipolar Lead Systems

Unipolar lead systems are not recommended because they are more susceptible to electromagnetic interference, which may result in inappropriate pacing. Unipolar lead systems should not be used in the dual-chambered pacing modes because the current path of one lead system may interfere with the current path of the other.

Atrial Sensing

The atrial sensing threshold should be evaluated to ensure maximum electrogram amplitude and that an adequate atrial sensing threshold is obtained prior to programming to a mode that requires atrial sensing (DDD, DDI, or AAI).

Place the wires on the right atrial free wall, oriented along the direction of the myocardial fibers, approximately 1 cm apart. It is important to achieve a sensing threshold of at least 1.0 mV. The atrial sensitivity should be set to a minimum of one-half the measured threshold. This ensures a minimum safety margin of 2x the sensing threshold. Failure to follow this procedure can lead to delivery of asynchronous pulses.

Sensitivity Settings

Since the sensitivity setting determines the smallest signal that can be sensed by the pacemaker, set the sensitivity dial to one-half the mV value of the patient's sensitivity threshold (see "Sensing Threshold" on page 82). This setting will provide a 2x safety margin to ensure proper sensing.

A more sensitive setting may be chosen to provide a greater safety margin. However, be aware that setting the sensitivity value too low (too sensitive) could result in inappropriate sensing of far field signals (e.g., sensing of R- or T-waves on the atrial channel or P-waves on the ventricular channel), leading to inappropriate inhibition of pacing pulses.

High Output and Maximum Sensitivity

Although the pacemaker contains a safety pacing feature that prevents inappropriate inhibition of ventricular pacing due to far-field sensing, the simultaneous use of high output and maximum sensitivity (i.e., the lowest mV value) should be avoided.

Electrostatic Discharge (ESD)

The pacing lead(s) provides a low-impedance pathway to the heart. Therefore, it is recommended that attending health care professionals discharge any static electricity by touching a large metal or conductive, grounded surface prior to touching the patient, the cable, the leads or the pacemaker. Also, neutralize any static electricity from the patient by touching the patient away from (i.e., distal to) the leads.

Retrograde Conduction

If retrograde P-waves are being sensed outside the rate-dependent, automatic Post-Ventricular-Atrial-Refractory Period (PVARP) setting, manually increase the PVARP until the retrograde waves fall inside the PVARP. Failure to follow this procedure may lead to a pacemaker mediated tachycardia (PMT).

Termination of Pacing

Abrupt termination of pacing stimuli may result in intervals of asystole before an intrinsic rhythm is reestablished. Prior to terminating pacing, set the pacemaker to a demand mode, then gradually reduce the pacing rate below the patient's intrinsic rate.

PAUSE Key

Use the **PAUSE** key with care, since the patient is without pacing support (for a maximum of 10 seconds at a time) when **PAUSE** is pressed and held.

A-V Interval

Programming long A-V intervals may result in pacing the ventricle during the vulnerable period of ventricular repolarization, thus precipitating ventricular arrhythmias in unstable patients.

EMERGENCY Key

Use the **EMERGENCY** key only when high-output asynchronous pacing (DOO) is needed. When the **EMERGENCY** key is pressed, the emergency pacing mode is entered and remains in effect until the emergency pacing mode is deactivated. Press the **ON** key to deactivate emergency pacing mode. For more information, see "EMERGENCY (ASYNC.) Key" on page 27.

Environmental Precautions

The Model 5388 has been carefully designed and tested to ensure reliability during normal use. However, electronic devices are susceptible to many environmental stresses. Precautions should be taken to avoid damage to the unit, including (but not limited to) the precautions listed in this chapter.

- Do not drop the unit or handle it in a way that might physically damage the device. The device may appear to work appropriately immediately after being dropped or mishandled, but operational damage may have occurred.
- Do not place the Model 5388 in any area where a patient may interact with it. Tampering with programmed parameters may have direct and serious patient health effects. The temporary pacemaker should be placed in an area that minimizes tampering with the device by unauthorized personnel (patients, visitors, etc.). Medtronic recommends the use of a protective cover, such as the Medtronic Model 5441 clear plastic cover, to minimize tampering.
- Avoid spilling fluid on the unit. The Model 5388 was carefully designed to minimize leakage, but fluid incursion may still occur. Medtronic recommends the use of a protective cover, such as the Medtronic Model 5409 plastic pouch, to minimize fluid incursion.
- Avoid contaminating the safety cable receptacle and connector pin receptacles with blood or other body fluids.
- Always use safe electrostatic discharge (ESD) procedures; this device could be adversely affected by ESD.
- Do not open the device. The seam joining the unit is designed to minimize fluid incursion and may not be effective if improperly opened and resealed. Furthermore, removing the label on the back of the unit may compromise the ESD barrier. Opening this unit will void the warranty (see “Limited Warranty” on page 106).
- Do not sterilize the Model 5388 by gamma irradiation or steam (autoclave). See “Cleaning and Sterilization” on page 96 for more information.
- Rapid temperature changes may affect proper operation. Always allow the temperature of the device to stabilize in the environment in which the device will be used before attachment and operation (see page 102 for recommended storage and operation temperatures).

- Prolonged storage or operation of the device in high humidity may affect proper operation. Allow the device to completely dry after exposure to humidity.

Other environmental factors may impact proper performance of the unit in the hospital setting. Use of appropriate environmental health and safety practices will help prevent environmental damage to the unit.

Adverse Effects

Temporary Pacemakers

Potential adverse effects related to the use of temporary external pacemakers such as the Model 5388 include, but are not limited to:

- Asystole following abrupt cessation of pacing;
- Inhibition or reversion in the presence of strong electromagnetic interference; and
- Initiation of a tachyarrhythmia or acceleration of an existing tachyarrhythmia.

Atrial High-Rate Burst Pacing

Atrial high-rate burst pacing may result in the onset of tachycardia, acceleration of an existing tachycardia, or fibrillation. Application of temporary atrial high-rate burst pacing should be performed in a carefully monitored and controlled patient environment. Monitor the patient's ECG and blood pressure, and keep defibrillation equipment on standby, immediately available for emergency use.

Dual Chamber Modes

In the DVI, DDI, and DDD modes, the ventricular sense amplifier may sense the atrial pacing pulse. Reducing the atrial amplitude, the ventricular sensitivity, and/or repositioning the electrodes may be necessary to avoid this situation.

Safety Margins

Determine an adequate safety margin for sensing and pacing in both the ventricle and atrium (see Chapter 5). Failure to do so may result in inappropriate pacing.

Lead Systems

Potential adverse effects related to the use of pacing lead systems used in conjunction with the Model 5388 temporary pacemaker include, but are not limited to:

- Inappropriate lead connections;
- Inadvertent disconnection of the lead system;
- Lead fracture or displacement causing intermittent or complete loss of capture and/or sensing; and
- Perforation and tamponade.

Other potential adverse effects related to the use of any implanted lead system include, but are not limited to:

- Myocardial irritability resulting in fibrillation;
- Infarction;
- Pericarditis;
- Body rejection phenomena (local tissue reaction);
- Muscle and nerve stimulation; and
- Infection.

Nerve or muscle stimulation can be caused by pacing lead contact with the nerve or muscle tissue and/or by high-output settings. The stimulation may be controlled by repositioning or replacing the electrode, or by reducing the output pulse amplitude.

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Controls

The dials and keys used to control the functions and parameter settings of the Model 5388 are described below.

Note: All adjustments to the **RATE**, **A** (Atrial) **OUTPUT**, and **V** (Ventricular) **OUTPUT** dials take effect within the next two pacing cycles.

Lock/Unlock Key

This key allows the user to “lock” and “unlock” the upper screen parameter values, **RATE**, **A OUTPUT**, and **V OUTPUT** (see “Lock Feature” on page 47).

When the upper screen is unlocked, press this key to lock the upper screen parameters at their current settings. The backlight will turn off and the lock indicator appears in the upper right-hand corner of the upper screen. Pressing this key while a lower menu is active causes the device to exit the menu.

Note: If this key is not pressed, the device automatically locks the parameters on the upper screen 60 seconds after the last device adjustment, with the exception of Menu **3**. When in Menu **3** (Rapid Atrial Pacing), the device waits five minutes before locking.

When the upper screen is locked, press this key to unlock the upper screen, allowing the upper screen parameters to be adjusted again. The backlight turns on, unless the low battery indicator is flashing (see “Low Battery Indicator” on page 31).

1. Pace/Sense LEDs
2. Lock/Unlock Key
3. Lock Indicators
4. Rate Dial
5. Atrial Output Dial
6. Ventricular Output Dial
7. Menu Parameter Dial
8. Parameter Selection Key
9. Menu Selection Key
10. Pause Key
11. Power On Key
12. Power Off Key
13. Emergency/Asynchronous Pacing Key
14. Lower Screen
15. Ventricular Output Graphics
16. Atrial Output Graphics
17. Upper Screen
18. Rate Graphics
19. Setup Indicators
20. DDI Indicator
21. Low Battery Indicator
22. Setup Labels

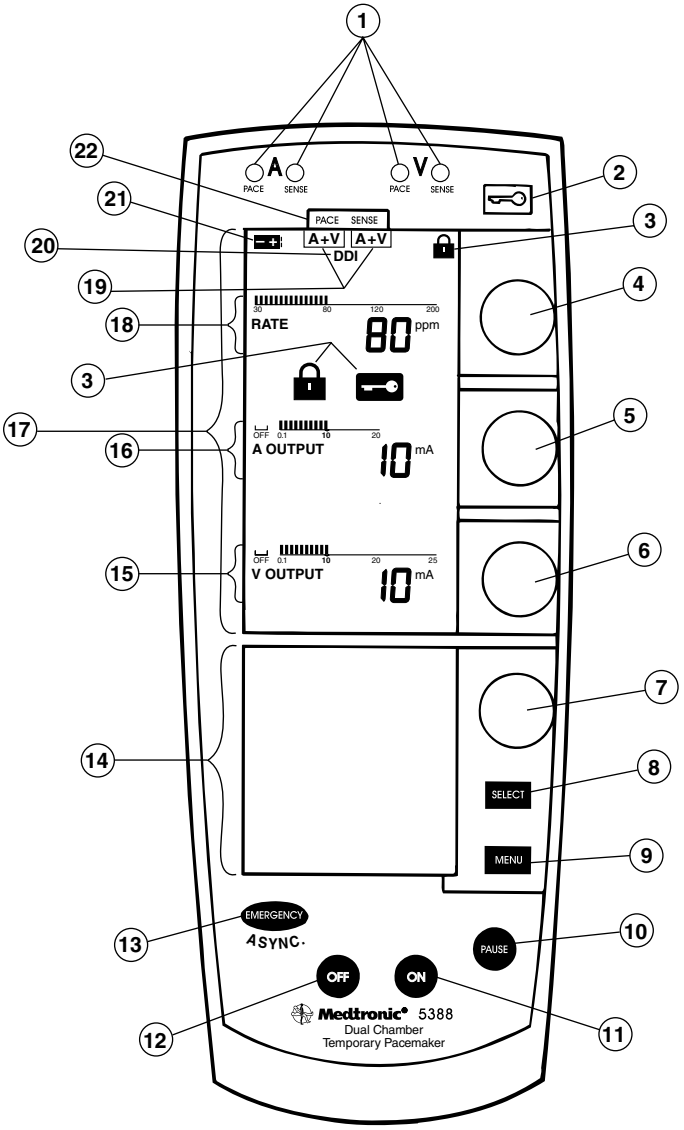


Figure 3-1. Controls and Indicators of the Model 5388.

ON Key

Press the **ON** key once to power the device up. The device first senses, then begins sensing and pacing in both chambers (DDD mode).

The upper screen and the backlight illuminate and a self-test is initiated (see “Self-test” on page 48). After the self-test is successfully completed the following occurs:

- If the battery has sufficient power, the device begins sensing and pacing in both the atrium and ventricle at the following nominal parameter values:

Table 3-1. Power-on values.

Base **RATE**	80 min^{-1}
A OUTPUT and **V OUTPUT**	10 mA
Atrial pulse width	1.0 ms[a]
Ventricular pulse width	1.5 ms[a]
A SENSITIVITY	0.5 mV
V SENSITIVITY	2.0 mV
A TRACKING[b]	ON
UPPER RATE[c]	110-min^{-1}
PVARP[c]	300 ms
A-V INTERVAL (paced)[c]	170 ms

[a] Pulse width is not adjustable.

[b] For a description of atrial tracking, see page 38.

[c] These parameters are set to the automatic, rate-dependent values (see “Device Specifications” on page 101).

- If the battery is nearing depletion, the low-battery indicator is displayed.
- If the battery is depleted, the **LEDs** may come on (see “Light-Emitting Diodes” on page 30) while **ON** is pressed, but the device will not operate.

When the upper screen is locked, press the **ON** key once to unlock the upper screen (see “Lock/Unlock Key” on page 24). The backlight comes on and the upper screen parameters may be adjusted. The device continues to pace at the currently selected values.

When the device is pacing asynchronously, to return the device to demand (synchronous) pacing:

- Press the **ON** key *once* if the asynchronous pacing message (see page 28) is displayed in the lower screen.
- Press the **ON** key *twice* if the asynchronous pacing message is not displayed in the lower screen. (After the first press of the **ON** key, the asynchronous pacing message appears).

The device begins pacing synchronously at the following values:

Table 3-2. ON key synchronous values.

RATE	current setting
A OUTPUT and **V OUTPUT**	current settings
A SENSITIVITY **V SENSITIVITY**	0.5 mV (nominal)[a] 2.0 mV (nominal)[a]

[a] If the corresponding **OUTPUT** is not **OFF**.

OFF Key

To turn the device off, press the **OFF** key twice within 5 seconds. (After the first press, a message appears in the lower screen telling the user to press **OFF** a second time to turn the device off.)

- The backlight turns off, the screens blank, and three **LEDs** illuminate, then turn off, when **OFF** is pressed the second time.

Note: If the **OFF** key is pressed **once** when the upper screen parameters are locked:

- The backlight illuminates and the upper screen unlocks, allowing the parameters to be adjusted.
- The lower screen displays the message telling the user to press **OFF** a second time (Ignoring this message allows the device to continue pacing at the currently selected values).

EMERGENCY (ASYNC.) Key

A single press of this key selects high-output, dual-chamber asynchronous pacing (DOO) at any time, including when the device is off. Avoid accidentally activating the Emergency key.

Note: Asynchronous pacing can also be reached by adjusting **A** and **V SENSITIVITY** on Menu **1** (see “Menu 1” on page 36).

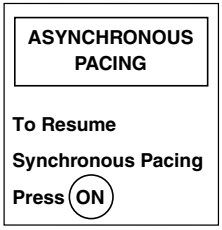
To initiate dual-chamber asynchronous pacing, press the **EMERGENCY/ASYNC**. key once at any time (that is, while the device is on, off, in a Menu or locked). The device will pace at the following values:

Table 3-3. Emergency values.

RATE	current setting, or 80 min^{-1} if device was off
A OUTPUT	20 mA
V OUTPUT	25 mA
A SENSITIVITY	**ASYNC** (i.e., no sensing)
V SENSITIVITY	**ASYNC** (i.e., no sensing)
A TRACKING, UPPER RATE, PVARP	not applicable
A-V INTERVAL	automatic rate-dependent, or current manual setting

Note: If the device is locked when **EMERGENCY/ASYNC**. is pressed, the upper screen parameters unlock, the backlight turns on and the device immediately begins to pace at emergency values.

The **RATE**, **A OUTPUT**, and **V OUTPUT** can be adjusted using the three upper dials. The **A-V INTERVAL** can be manually adjusted or allowed to adjust automatically with the **RATE** (see "A-V Interval" on page 38).



The message to the left appears in the lower screen.

Note: The asynchronous pacing message disappears after one minute. The message reappears anytime the **ON** key is pressed (see "ON Key" on page 26) during asynchronous pacing.

To resume demand (synchronous) pacing, press the **ON** key (see "ON Key" on page 26), or access Menu **1** and adjust **A SENSITIVITY** and/or **V SENSITIVITY** (see page 37).

PAUSE Key

This key interrupts pacing and sensing to allow the user to view the patient's intrinsic rhythm.

△ **Caution:** Use the **PAUSE** key with care, since the patient is without pacing support (for a maximum of 10 seconds at a time) when **PAUSE** is pressed and held.

When the **PAUSE** *key is pressed and held,* the device stops pacing and sensing for a maximum of 10 seconds. The message to the left appears in the lower screen, reminding the user that pacemaker operation is suspended.

To suspend device operation for up to another 10 seconds, release, then press and hold the **PAUSE** key again. Repeat this as many times as required.

When the **PAUSE** *key is released,* the device first senses, then resumes pacing at the programmed parameters. The device also senses before pacing if **PAUSE** times out at 10 seconds.

If the **PAUSE** *key is pressed when the upper screen is locked,* pacing and sensing are suspended, as described above, and the upper screen parameters unlock.

MENU Key

The **MENU** key is used to activate and page through the Menus on the lower screen, from Menu **1** to Menu **M**.

If pressed when the upper screen is locked, the Menu screen becomes active, and the upper screen parameters unlock.

SELECT Key

The **SELECT** key is only active when the Menu screens are active.

In Menus 1 and 2 – Use the **SELECT** key to scroll through the parameters continuously, from top to bottom and back to the top.

In Menu 3 (Rapid Atrial Pacing) – Press and hold the **SELECT** key to deliver a Rapid Atrial Pacing burst (see page 42).

In Menu M (DIAL-A-MODE) – Use the **SELECT** key to activate a new mode (see page 44).

Rate Dial

The top dial is used to set the base rate at which pacing pulses are delivered, in reciprocal minutes (min^{-1}) (see “RATE” on page 33).

Atrial Output Dial

The Atrial Output dial is the second dial from the top. It is used to set the current amplitude, in milliamps (mA), of the atrial pacing pulse [see “A (Atrial) OUTPUT” on page 34].

Ventricular Output Dial

The Ventricular Output dial is the third dial from the top. It is used to set the current amplitude, in mA, of the ventricular pacing pulse [see “V (Ventricular) OUTPUT” on page 34].

Menu Parameter Dial

The Menu Parameter Dial is the fourth dial from the top. It is used to adjust the parameters displayed on the Menu Screens (see “Lower Screen” on page 35).

Light-Emitting Diodes

All light-emitting diodes (LEDs) are illuminated during the Power-on Self-test.

PACE LEDs

There are two green LEDs at the top of the device, marked **PACE**.

- The green LED next to the **A** flashes each time the device delivers a pacing pulse on the atrial channel.
- The green LED next to the **V** flashes each time the device delivers a pacing pulse on the ventricular channel.

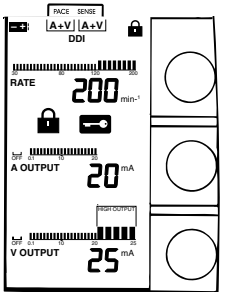
Note: These LEDs indicate delivery of a pacing pulse but do not necessarily indicate that the pacing pulse has initiated cardiac stimulation.

SENSE LEDs

There are two orange LEDs at the top of the device, marked **SENSE**.

- The orange LED next to the **A** illuminates when events are sensed on the atrial channel. The **A SENSE LED** flashes when the device detects events inside and outside the atrial refractory period.
- The orange LED next to the **V** illuminates when events are sensed on the ventricular channel. The **V SENSE LED** flashes only when the device detects an event outside the refractory period.

Upper Screen



The upper screen displays:

- Indicators:
  - Low Battery Indicator
  - Pacemaker Setup Indicators
  - Lock Indicators
  - DDI Indicator
- Parameters for basic pacing:
  - **RATE**
  - **A** (Atrial) **OUTPUT**
  - **V** (Ventricular) **OUTPUT**

When the device is off, the upper screen is blank, except for the number lines, which are painted on the glass.

When the device is on, the numerical and graphical values for the parameters appear, and the screen is illuminated by a backlight. The backlight remains on while parameters are adjusted but is turned off 60 seconds after the last adjustment even while Menu 3 (RAP) is active [see “Menu 3 (Rapid Atrial Pacing)” on page 42].

Indicators

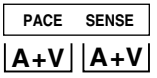
Low Battery Indicator

This indicator comes on and flashes when the battery reaches replacement time.

When the Low Battery indicator begins to flash during device operation, the device will operate satisfactorily for a minimum of 24 hours at or below a **RATE** of 70 min^{-1}, nominal **OUTPUTs**, and with the lower screen inactive (“Nominal Values” on page 102). The backlight will not illuminate once the low battery indicator appears.

To extinguish the Low Battery indicator, replace the low battery (see “Battery Installation” on page 56) with a recommended new 9-Volt battery.

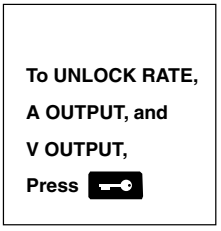
Pacemaker Setup Indicators



The **PACE** and **SENSE** labels painted on the light gray bar *above* the upper screen, and the **A** and **V** indicators that appear *on* the screen below the labels communicate to the user which chambers (**A** for atrium, **V** for ventricle) the device is currently set to pace and/or sense. These indicators can be used to determine the current pacing mode (see “Model 5388 Pacing Setup Table.” on page 92).

Note: The Setup Indicators do not indicate actual device interaction with the heart.

Lock Indicators



A [🔒] appears when the upper screen parameters are “locked”. If upper dials are turned while the parameters are locked, this indicator remains on, and a [🔒] and a flashing [⊟] appear in the upper screen between **RATE** and **A OUTPUT**. The message to the left appears in the lower screen.

The lower screen message and the two icons in the center of the upper screen disappear after approximately 15 seconds if nothing is done to unlock the upper screen parameters. All three indicators disappear when the parameters are unlocked (see “Lock Feature” on page 47).

DDI Indicator

This indicator appears below the Pacemaker Setup Indicators when the device is pacing and sensing in both chambers, but **A** (Atrial) **TRACKING** is turned **OFF** [see “A (Atrial) TRACKING” on page 38].

Parameters

The **RATE**, **A OUTPUT**, and **V OUTPUT** settings are displayed both numerically and graphically. The line next to each dial shows the range available for that parameter. Line segments appear, showing where, within the range, the parameter is set. The setting's numerical value appears just below the segmented line graph.

RATE

The base pacing rate ranges from 30 to 200 min^{-1} and is incremented as in Table 3-4.

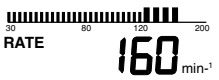
Table 3-4. Rate Increments.

Range	Increment
30 to 50 min^{-1}	5 min^{-1}
50 to 100 min^{-1}	2 min^{-1}
100 to 200 min^{-1}	5 min^{-1}

Turn the top dial clockwise to increase **RATE**, and counter-clockwise to decrease **RATE**.

A+V A+V

The (nominal) **RATE** setting at which the device powers up is 80 min^{-1}.



For rates above 120 min^{-1}, the line segments become taller and wider to warn the user that **RATE** is set above the typical range.

Note: The rate-dependent parameters **UPPER RATE**, **PVARP**, and **A-V INTERVAL** are automatically adjusted each time **RATE** is adjusted unless they are manually set (see "Menu 2" on page 39).

A (Atrial) OUTPUT

The atrial output ranges from 0.1 to 20 mA, and is incremented as in Table 3-5.

Table 3-5. Atrial Output Increments.

Range	Increment
0.1 to 0.4 mA	0.1 mA
0.4 to 1.0 mA	0.2 mA
1.0 to 5 mA	0.5 mA
5 to 20 mA	1.0 mA

Turn the dial clockwise to increase **A OUTPUT**. Turn the dial counterclockwise to decrease or turn **A OUTPUT OFF**. The space above **OFF** fills in when **A OUTPUT** is turned **OFF**.

When **A OUTPUT** i*s set to* **OFF**, both the atrial output and the atrial sensitivity are turned off (i.e., there is no atrial pacing or sensing). If **A OUTPUT** is turned back on within approximately seven seconds, atrial sensitivity is set to the previously selected value. If **A OUTPUT** is **OFF** for longer than approximately seven seconds, atrial sensitivity is set to the nominal value of 0.5 millivolts (mV) when **A OUTPUT** is turned back on.

Note: A SENSITIVITY can be adjusted from Menu **1** on the lower screen [see “A (Atrial) SENSITIVITY” on page 37].

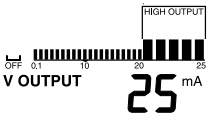
At power up, **A OUTPUT** is 10 mA (nominal), **A SENSITIVITY** is 0.5 mV (nominal), and pulse width is fixed at 1.0 ms.

V (Ventricular) OUTPUT

The ventricular output ranges from 0.1 to 25 mA, and is incremented as in Table 3-6.

Table 3-6. Ventricular Output Increments

Range	Increment
0.1 to 0.4 mA	0.1 mA
0.4 to 1.0 mA	0.2 mA
1.0 to 5 mA	0.5 mA
5 to 25 mA	1.0 mA



Turn the dial clockwise to increase **V OUTPUT**. Turn the dial counterclockwise to decrease or turn **V OUTPUT** to **OFF**. The space above **OFF** fills in when **V OUTPUT** is turned **OFF**.

If **V OUTPUT** is set above 20 mA, the line segments becomes taller and wider and an icon with the message, "**HIGH OUTPUT**," appears above the taller segments.

When **V OUTPUT** *is set to* **OFF**, both the ventricular output and the ventricular sensitivity are turned off (i.e., there is no ventricular pacing or sensing). If **V OUTPUT** is turned back on within approximately 7 seconds, ventricular sensitivity is set to the previously selected value. If **V OUTPUT** is **OFF** for longer than approximately 7 seconds, ventricular sensitivity is set to the nominal value of 2.0 millivolts (mV) when **V OUTPUT** is turned back on.

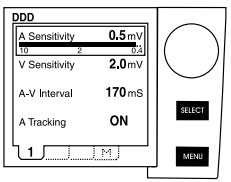
Notes:

- **V SENSITIVITY** can be adjusted using Menu **1** on the lower screen [see "V (Ventricular) SENSITIVITY" on page 37].
- **V OUTPUT** is set to **OFF** when the **SELECT** key is pressed for RAP delivery [see "Menu 3 (Rapid Atrial Pacing)" on page 42]. **V OUTPUT** returns to its previous value when **SELECT** is released.

At power-up **V OUTPUT** is 10 mA (nominal), **V SENSITIVITY** is 2.0 mV (nominal), and pulse width is fixed at 1.5 ms.

Lower Screen

Functions



The Lower Screen has two functions:

- To display warnings and instructions, and
- To provide access to the four Menus:
  - **MENU 1**: Allows adjustment of **A** (Atrial) and **V** (Ventricular) **SENSITIVITY**, the **A-V INTERVAL**, and **A** (Atrial) **TRACKING**.
  - **MENU 2**: Allows adjustment to the rate-dependent parameters **UPPER RATE**, **PVARP**, **A-V INTERVAL**, and to a feature called **SETTING**.
  - **MENU 3**: Allows access to Rapid Atrial Pacing (RAP).

– **MENU M**: **DIAL-A-MODE** allows direct selection of DDD, DVI, DOO, or VVI mode.

Controls

The controls for the Menus and their parameters are:

- **MENU PARAMETER** dial.
- **SELECT** key, and
- **MENU** key.

While the Menus in the lower screen are in use, the upper screen remains unlocked, and the upper screen parameters may be adjusted at any time using the corresponding dial.

Press [⊟] to exit the Menus.

Status Line

The NASPE and British Pacing and Electrophysiology Group (NBG) code is displayed at the top of every Menu and is updated when parameter adjustments cause a mode change (see page 93 and “Pacemaker diagnostic diagrams” on page 107 for information on NBG codes).

The phrase “***MANUAL**” appears at the top of every Menu screen if one or more of the three rate-dependent parameters are manually adjusted (see “SETTING” on page 42).

Note: Once activated, if Menu **1**, **2**, **M**, and the upper screen parameters remain unchanged for over 60 seconds, the menu goes blank. Menu **3** goes blank five minutes after the last adjustment or RAP delivery.

Menu 1

This Menu provides access to the:

- Atrial sensitivity (**A SENSITIVITY**),
- Ventricular sensitivity (**V SENSITIVITY**),
- A-V Interval (**A-V INTERVAL**), and
- Atrial tracking option (**A TRACKING**).

These parameters are displayed both numerically and graphically.

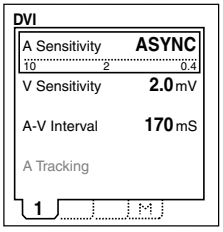
Parameters that do not apply to the current chambers being paced and sensed are less visible (i.e., grayed out) and are not selectable. To change grayed-out parameters, the chambers being paced and sensed (i.e., the pacing mode) must first be changed (see “Model 5388 Pacing Setup Table.” on page 92).

A (Atrial) SENSITIVITY

Unless manually adjusted, the atrial sensitivity (**A SENSITIVITY**) is set to the nominal value of 0.5 mV.

When selected, the **A SENSITIVITY** may be adjusted between 0.4 and 10 mV by turning the **MENU PARAMETER** dial.

Turn the dial clockwise to increase **A SENSITIVITY** (the mV value decreases), and counterclockwise to decrease **A SENSITIVITY** (the mV value increases). The change will take effect within the next two pacing cycles.



A SENSITIVITY *can be turned off*, allowing the pacemaker to pace asynchronously in the atrium, by turning the **MENU PARAMETER** dial counterclockwise until the term, **ASYNC**, appears.

- The Setup Indicators at the top of the upper screen reflect the change by the absense of the **A** under **SENSE**, and the **A SENSE LED** will no longer flash.
- The NBG code at the top of the lower screen also reflects the change in mode (i.e., chamber(s) paced and sensed).

Note: Modes that are punctuated by “!?” should be avoided or adjusted to a clinically useful mode.

A SENSITIVITY is automatically set to **ASYNC** when:

- **EMERGENCY** is pressed,
- RAP is delivered, or
- DVI or DOO mode is selected from Menu **M**.

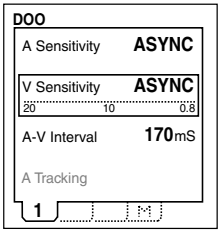
Note: A SENSITIVITY is inaccessible when **A OUTPUT** is turned to **OFF**.

V (Ventricular) SENSITIVITY

Unless manually adjusted, ventricular sensitivity (**V SENSITIVITY**) is set to the nominal value of 2.0 mV.

When selected, the sensitivity may be adjusted between 0.8 and 20 mV by turning the **MENU PARAMETER** dial.

Turn the dial clockwise to increase **V SENSITIVITY** (the mV value decreases), and counterclockwise to decrease **V SENSITIVITY** (the mV value increases). The change will take effect within the next two pacing cycles.



V SENSITIVITY *can be turned off*, allowing the pacemaker to pace asynchronously in the ventricle, by turning the **MENU PARAMETER** dial counterclockwise until the term, **ASYNC**, appears.

- The Setup Indicators at the top of the upper screen reflect the change by the absence of the **V** under **SENSE**, and the **V SENSE LED** will no longer flash.
- The NBG code at the top of the lower screen also reflects the change in pacing mode (i.e., chamber(s) paced and sensed).

Note: Modes that are punctuated by "!?" should be avoided or adjusted to a clinically useful mode.

V SENSITIVITY is automatically set to **ASYNC** when:

- **EMERGENCY** is pressed, or
- DOO mode is selected from Menu **M**.

Note: V SENSITIVITY is inaccessible when **V OUTPUT** is turned to **OFF**.

A-V Interval

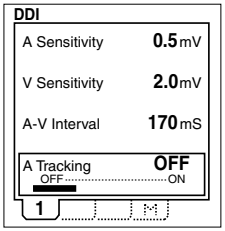
A-V INTERVAL may be adjusted from 20 to 300 ms in increments of 10 ms (see "A-V Interval" on page 41).

A (Atrial) TRACKING

This feature is only accessible or applicable when the device is set to sense and pace in both chambers. When **ON**, **A** (Atrial) **TRACKING** causes the device to pace the ventricle in synchrony with intrinsic atrial depolarizations.

When **A TRACKING** *is* **ON** (DDD mode), each sensed event on the atrial lead not only inhibits the scheduled atrial pacing pulse, but also triggers an **A-V INTERVAL**.

⚠ **Warning:** If a patient is prone to atrial arrhythmias, atrial tracking could lead to the development of ventricular arrhythmias (see "Contraindications" on page 10).



When **A TRACKING** *is* **OFF** (DDI mode), an atrial sense does not trigger an **A-V INTERVAL**. The ventricle is paced at the selected **RATE**.

To turn **A TRACKING OFF**, use **SELECT** to highlight the parameter, then turn the **MENU PARAMETER** dial counterclockwise until **OFF** replaces **ON**. Turn the **MENU PARAMETER** dial clockwise to turn **A TRACKING ON**.

Note: A TRACKING can be manually turned **OFF** only from DDD mode. **A TRACKING** can be manually turned **ON** only from DDI mode. However, **A TRACKING** is automatically set to **ON** when the mode changes from DDI to any other mode, regardless of its applicability in the new mode.

Menu 2

This Menu allows manual adjustment of these dual chamber, rate-dependent parameters:

- **UPPER RATE**,
- **PVARP** (post-ventricular atrial refractory period),
- **A-V INTERVAL** (appears on Menu **1** also), and
- **SETTING**, which is a toggle between automatic and manual settings for the rate-dependent parameters.

When not manually adjusted, these parameters are automatically set to a factor of the base pacing rate (see “Nominal Values” on page 102).

When manually set, the rate-dependent parameters do not change with adjustments to the **RATE**.

- If further increase of the **RATE** would cause a timing violation with the **UPPER RATE**, a warning message appears on the lower screen, and **RATE** is not allowed to be increased until **UPPER RATE** is increased (see “Timing Violations” on page 51).
- If further increase or decrease of the **RATE** would cause a timing violation with the **A-V INTERVAL** or **PVARP**, a warning message appears on the lower screen and **RATE** is not allowed to be adjusted until **A-V INTERVAL** and/or **PVARP** are adjusted (see “Timing Violations” on page 51).

During manual adjustments, if a rate-dependent parameter is adjusted to a point where further adjustment would cause a timing violation (see “Timing Violations” on page 51), a warning message will overwrite the Menu for 10 seconds. During those 10 seconds, either:

- Adjust the **RATE**, or
- Press the **MENU** key to activate Menu 2 and adjust the rate-dependent parameter.

After 10 seconds the message will disappear, and the device will continue operating at the currently selected parameter values.

Upper Rate

This parameter is designed to set the maximum ventricular pacing rate allowed while tracking the atrium. At sensed atrial rates above the **UPPER RATE**, a Wenckebach-type response results (see page 50). This parameter is adjustable only in dual chamber modes with atrial tracking.

Unless manually adjusted, this parameter is limited to the range of 110 to 230 min^{-1} and is determined by the **RATE** setting using the following formula:

UPPER RATE = **RATE** + 30 min^{-1}

When selected on Menu **2**, however, the **UPPER RATE** can be adjusted to values from 80 to 230 min^{-1} incremented as follows:

Table 3-7. Upper Rate increments.

Rate	Increment
80 to 130 min^{-1}	2 min^{-1}
130 to 230 min^{-1}	5 min^{-1}

PVARP (Post Ventricular Atrial Refractory Period)

This parameter sets the length of time following a ventricular event during which atrial sensing does not affect pacemaker timing. **PVARP** is designed to prevent the device from responding to atrial sensing of ventricular activities such as far-field R-waves, PVCs, and retrograde conduction.

Unless manually adjusted, this parameter is determined by the base pacing rate as shown in Table 3-7.

Table 3-8. Default PVARP settings.

Rate	PVARP
≤100 min^{-1}	300 ms
105 to 150 min^{-1}	250 ms
155 to 180 min^{-1}	225 ms
>180 min^{-1}	200 ms

The **PVARP** *can be manually adjusted* to any value, from 150 ms to 500 ms in 10 ms increments, that does not cause a timing violation (see “Timing Violations” on page 51).

Note: If PVARP is set to 150 ms, atrial events may not be sensed due to the tolerance allowed for blanking after a paced event (see “Blanking” on page 101)

A-V Interval

Displayed on both Menu **1** and Menu **2**, the A-V Interval after an atrial *pace* (i.e., PAV, or **A-V INTERVAL**) is the amount of time, in ms (milliseconds), that the pacemaker waits between the delivery of an atrial pacing pulse and delivery of the corresponding ventricular pacing pulse.

Note: The A-V Interval after an atrial *sensed* event (i.e., SAV) is not programmable. The SAV is automatically set to a value 30 ms less than the **A-V INTERVAL**.

Unless manually adjusted, **A-V INTERVAL** is set to a value determined by the **RATE** setting. It can never be shorter than 50 ms or longer than 250 ms, as determined by the following formula:

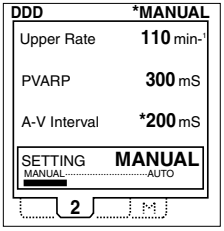
A-V INTERVAL ms = 300 – (1.67 x **RATE** min^{-1})

The final value is rounded off to the nearest higher multiple of 10, within the automatic range (i.e., 50, 60, 70, . . . 230, 240, 250). For example, at a **RATE** of 70 min^{-1}, the **A-V INTERVAL** would be rounded to 190 ms.

When selected on Menu **1** *or* **2**, however, the **A-V INTERVAL** can be manually set to values from 20 to 300 ms (in 10 ms increments) that do not cause a timing violation (see “Timing Violations” on page 51).

Note: If **A-V INTERVAL** is set shorter than 50 ms, ventricular events may not be sensed during that interval, due to ventricular blanking after an atrial event.

SETTING



This feature sets the **A-V INTERVAL**, **UPPER RATE**, and **PVARP** to automatic, rate-dependent settings (see “Auto” on page 101).

SETTING is inaccessible (grayed-out) when the device is using automatic settings. When a Menu **2** parameter (or **A-V INTERVAL** on Menu **1**) has been manually adjusted:

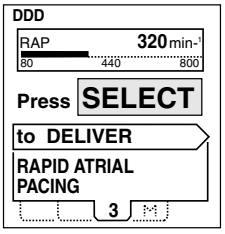
- The word “**MANUAL**” appears to the right of SETTING and at the top of the lower screen with an asterisk (*),
- An asterisk (*) appears next to the value of each setting which has been manually adjusted, and
- **SETTING** becomes accessible.

To change **A-V INTERVAL***,* **UPPER RATE***, and* **PVARP** *back to automatic*, rate-dependent settings, select **SETTING** and turn the **MENU PARAMETER** dial clockwise until **AUTO** replaces **MANUAL**.

The user can use the **MENU PARAMETER** dial to alternate between **AUTO** and **MANUAL** parameter settings, as long as **SETTING** remains selected (turn the dial counterclockwise to reinstate ***MANUAL** values). Previous **MANUAL** settings are lost if the user sets the parameters to **AUTO** and then adjusts an upper or lower screen parameter.

Note: The rate-dependent parameter values are immediately updated on the screen and go into effect at the next appropriate event when switching **SETTING** from **AUTO** to **MANUAL**, or **MANUAL** to **AUTO**.

Menu 3 (Rapid Atrial Pacing)



This Menu enables the Rapid Atrial Pacing (RAP) feature, but the device continues to operate at the **RATE**, **A OUTPUT**, **V OUTPUT**, and mode on the upper screen until the **SELECT** key is pressed.

When Menu **3** *is accessed,* the RAP screen displays either:

- the most recent RAP rate used, or
- the nominal RAP rate of 320 min^{-1} if RAP has not been used since the device has been powered **ON**.

The RAP rate is displayed numerically and graphically, and can be adjusted between or during RAP delivery by turning the **MENU PARAMETER** dial.

When **SELECT** *is pressed and held,* the device waits a maximum of two pacing cycles, then begins pacing asynchronously in the atrium (AOO) at the selected RAP rate.

When **SELECT** *is released*, the device stops delivering RAP and resumes operation at the non-RAP settings, within three seconds. The device senses before pacing when resuming operation in a demand mode.

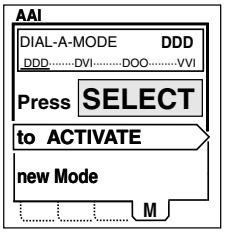
A OUTPUT may be adjusted during RAP delivery. **V OUTPUT** is **OFF** and not accessible during RAP delivery. **V OUTPUT** returns to its previous value when **SELECT** is released.

Notes:

- If the device should continue to deliver RAP after the SELECT key is released, press **OFF** or **EMERGENCY** to stop RAP. Return the device for service.
- If **A OUTPUT** is **OFF** prior to RAP delivery, **A OUTPUT** is set to 10 mA when **SELECT** is pressed. In this case, **A OUTPUT** may be adjusted during RAP delivery, but returns to **OFF** when **SELECT** is released.
- The backlight turns off 60 seconds after the last adjustment or RAP delivery, but the upper screen parameters do not lock and Menu **3** does not blank. Each time an upper dial or the **SELECT** key is used, the backlight turns on again.
- The upper screen parameters do not lock, and the lower screen does not blank until five minutes after the last adjustment or RAP delivery.

To exit Menu **3** (RAP) before five minutes have passed, press the [⊷] key or the **MENU** key.

Menu M (Dial-A-Mode)



This Menu allows the user to select:

- DDD, DVI, DOO, or VVI pacing mode.

When the mode is underlined, the message to the left appears and an arrow points to the **SELECT** key.

- Turn the **MENU PARAMETER** dial to underline the desired mode.
- Press the **SELECT** key.

The new mode is activated within the next two cycles. The **PACE** and **SENSE LEDs**, the Setup Indicators at the top of the upper screen, and the NBG code at the top of the Menu screens reflect this change.

The new mode will retain the current setting of all applicable parameters of the previous mode, if no timing violations occur. If timing violations occur, the rate-dependent parameters will be set to automatic values (see “Timing Violations” on page 51).

Parameters that did not apply in the previous mode will be set to nominal values in the new mode (see “Pacing Mode Transitions” on page 50).

Physical Features

Battery

Battery Drawer – The battery drawer, located on the lower right side of the device, accepts a standard 9-volt alkaline or lithium battery (see “Battery Type” on page 103).

Battery Life – Battery life is typically 9 days, minimally 7 days, continuous operation for an alkaline battery or approximately 16 days continuous operation for a lithium battery, when **RATE** is set at 70 min^{-1} and all other parameters are at nominal values (see “Nominal Values” on page 102).

Battery Drawer Release Button – Press the button at the lower end of the device to open the battery drawer.

Reversible Battery Polarity – The polarity is marked inside the battery drawer; however, the device will also function properly if the battery is installed with the polarity reversed.

Continued Operation After Battery Removal – If the battery is removed, the device will continue to operate for 15 seconds, typical (see “Operation After Battery Removal” on page 103), under the following conditions: **RATE** of 70 min^{-1} or less, **A OUTPUT** and **V OUTPUT** of 10 mA or less, backlight off, and lower screen blank.

Note: If the battery is removed while the backlight is on or the lower screen is active, the device may shut down immediately depending upon the battery level.

Connector Block

Located at the top end of the device, the connector block has sockets which accept patient and surgical cables (Medtronic Patient Cable Models 5433A and 5433V and Medtronic Surgical Cable Models 5832 and 5832S). Chamber designations are marked A for atrium and V for Ventricle. The sockets are also color-coded blue for atrium and white for ventricle.

The connector block also has openings for the direct connection of heartwires or leads from 0.38 mm to 2.28 mm (0.015 inch to 0.09 inch) in diameter and from 12.67 mm to 22.8 mm (0.5 inch to 0.9 inch) in length. These connector pin receptacles are covered with removable rubber seals to minimize contamination. Chamber designations are marked **A** for atrium and **V** for ventricle. The receptacles are also color-coded blue for atrium and white for ventricle.

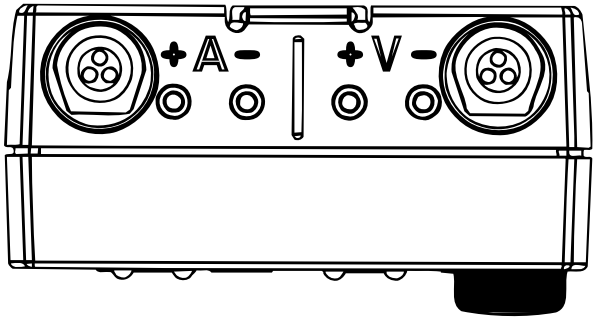


Figure 3-2. The Model 5388 Connector Block.

△ **Caution:** The connector pin receptacles are to be used in emergency situations only. They have no locking mechanism, so the retention force within the receptacles varies with pin diameter and length.

Attachment Ring and Bails

The attachment ring and bails are located on the back of the device. The ring is used to attach the device to an IV pole. The bails should only be used to temporarily secure the device to the patient or bed rail when the patient is in transit. When not in use, the ring and the bails fold flat against the back of the device.

1. Ring
2. Bails

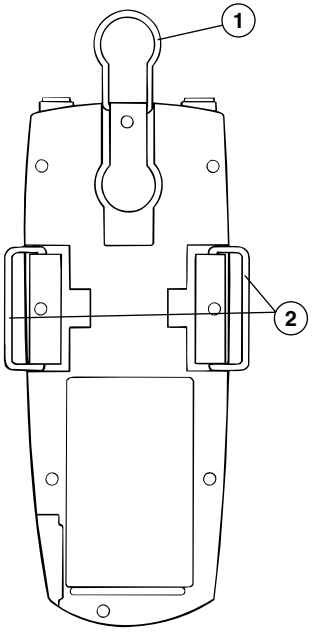


Figure 3-3. Ring and Bails on the Back Side of the Model 5388.

Functional Features

Lock Feature

This safety feature is intended to prevent inadvertent adjustment of the upper screen parameters **RATE**, **A OUTPUT**, and **V OUTPUT**.

Note: The **ON**, **OFF**, **EMERGENCY/ASYNC.**, **PAUSE**, and **MENU** keys do not lock.

When the upper screen is locked, turning the upper screen dials does not change the upper screen parameter values.

The upper screen parameters will lock:

- 60 seconds after the last parameter adjustment has been made, or
- When the [⊶] key is pressed.

When the upper screen is locked, the backlight turns off and a padlock [🔒] appears in the upper right corner of the upper screen.

If the upper dials are turned while the parameters are locked, the [🔒] remains on, the backlight illuminates, and a [🔒] and a flashing [⊶] appear in the center of the upper screen. The lower screen displays the message to the left.

To UNLOCK RATE, A OUTPUT, and V OUTPUT, Press ⊶

To unlock the upper parameters, press the [⊶] key.

If no action is taken to unlock the upper screen, and no other dial movements occur, the icons in the center of the upper screen disappear, the lower screen blanks, and the backlight turns off.

When the upper screen unlocks, all lock indicators on the upper screen disappear, the backlight illuminates, and the **RATE**, **A OUTPUT**, and **V OUTPUT** values can be changed again by turning the upper dials.

Notes:

- When the upper screen unlocks the backlight will not illuminate if the low battery indicator is on.
- If the **ON**, **OFF**, **EMERGENCY/ASYNC.**, **PAUSE**, or **MENU** key is pressed while the upper screen is locked, the upper screen parameters will unlock. However, changes in device operation and parameters may occur depending upon which key was pressed (see page 26 through page 29).

Self-test

When the Model 5388 is turned on, the device takes approximately four seconds to complete the power-on self-test and initialize the screens. The self-test includes a check of the **SELECT**, **OFF**, **PAUSE**, **MENU**, and **LOCK** keys, and critical internal circuits. The **PACE** and **SENSE LEDS** light one at a time during the Power-on Self-test.

During the self-test, information in the display buffer from the previous use of the device will appear on the upper display. This information is cleared during screen initialization and nominal values are restored.

Note: Pressing a key while the self-test is in process can cause the Model 5388 to fail the self-test, and display error code, “0004.” The device may interpret the pressed key as being “stuck” and, therefore, malfunctioning. If a key is pressed during the self-test, remove and re-insert the battery to clear the error code. If the self-test fails again, remove the battery and return the device to Medtronic for service (see the addresses on the back cover of the manual).

During screen initialization the low battery indicator may appear. This does **not** indicate that the battery is low, unless the backlight does not turn on and the indicator remains visible during device operation.

Sensing begins after successful completion of the self-test. Pacing begins approximately one second after sensing, if not inhibited by a sensed event.

Should the device fail the self-test, one of the **PACE** or **SENSE LEDS** remains on and no output pulses are issued. Failure codes may be displayed on the lower screen. Remove the battery. Return the device and battery for service (see the addresses on the back cover of the manual).

Note: Each time the **MENU** key is pressed the device checks the **SELECT** key. If the **SELECT** key is found to be stuck, the menus will not advance. Shut the device down by pressing **OFF** twice and return the device for service.

Blanking and Refractory Periods

Blanking Periods

Blanking is the interval following a paced or sensed event during which the device sense amplifier is disabled.

Blanking following paced events lasts longer than blanking following sensed events (see the specifications on “Blanking” on page 101).

Refractory Periods

The refractory period is the interval during which a sensed event does not affect pacing timing. However, an event sensed inside refractory but outside blanking (i.e., a refractory sense) restarts blanking and refractory periods (see the “Pacemaker Diagnostic Diagrams”).

During refractory, a sensed event in the atrium causes the **A SENSE LED** to flash. However, a refractory sensed event in the ventricle does not cause the **V SENSE LED** to flash.

Atrial Refractory – The two types of atrial refractory periods in the Model 5388 are:

- Atrial Refractory Period, which is initiated by an atrial sense or pace, and
- Post-Ventricular Atrial Refractory Period (PVARP), which is initiated by a ventricular sense or pace.

Ventricular Refractory – The Model 5388 uses one type of ventricular refractory period:

- Ventricular Refractory Period, which is initiated by a ventricular pace or sense.

Reversion Operation

This safety feature is designed to prevent inappropriate pacing therapy during continuous interference, such as noise or arrhythmias. When sensed events are continuously detected by the pacemaker, the device reverts to predetermined modes until the interference stops.

This response occurs when refractory sensed events are continuously detected.

In single-chamber pacing, continuous refractory sensing will cause AAI to revert to AOO, and VVI to revert to VOO.

In dual-chamber pacing, continuous refractory sensing in the atrium causes the device to inhibit atrial pacing pulses. Continuous refractory sensing in the ventricle causes the device to pace asynchronously in the ventricle.

Ventricular Safety Pacing

This feature is intended to prevent improper inhibition of ventricular pacing pulses if a non-ventricular event (e.g., cross-talk, noise) is sensed by the ventricular lead. This feature functions when the device is operating in a mode that senses and paces in the ventricle, and paces in the atrium (DVI, DDI, and DDD).

If a ventricular sensed event is detected outside the 20 ms blanking window, but within 110 ms after an atrial paced event, a ventricular safety pacing (VSP) pulse is delivered 110 ms after the atrial pace if the **A-V INTERVAL** is greater than 110 ms. The ventricular pacing pulse is delivered at the **A-V INTERVAL** if the **A-V INTERVAL** is less than 110 ms (see “Pacemaker Diagnostic Diagrams”). The **V PACE LED** and the **V SENSE LED** flash within 15 ms of each other.

Wenckebach Response

In DDD mode, when the intrinsic atrial rate increases beyond the **UPPER RATE**, the device continues to lengthen the SAV interval until a P-wave falls within the **PVARP**, and thus is not sensed. Because the P-wave is not sensed, the SAV interval is not started, and a ventricular pace is not issued.

Pacing Mode Transitions

The Model 5388 switches modes in accordance with the following guidelines:

- When switching from an atrial-only mode to a mode involving an A-V Interval (which could be as short as 20 ms), the first ventricular pacing pulse will be inhibited to avoid pacing into a T-wave.

- A complete cycle of the current mode is allowed to expire before implementing a new mode.
- The device senses before pacing when switching from an asynchronous mode to a synchronous mode.
- **UPPER RATE** is implemented immediately after switching to DDD mode.
- Parameters that did not apply in the previous mode will be set to nominal (or rate-dependent) values in the new mode.

Timing Violations

If the relationship between two or more parameters reaches a point where improper pacing could occur, further change in the conflicting direction is prevented.

A summary of the timing violations not allowed by the 5388 follows.

Mode Changes

During a mode change, if one or more of the rate-dependent parameters was manually set in the previous mode to a value that will cause improper pacing to occur in the new mode, then the device changes the parameter to its automatic, rate-dependent setting.

Parameter Adjustments

During adjustments of the rate-dependent parameters, if the user tries to set the parameters to values that violate timing rules, a warning message will overwrite the Menu and stay on for 10 seconds (see the following paragraphs for the specific messages). During those 10 seconds, either:

- Adjust the **RATE**, or
- Press the **MENU** key to activate Menu 2 and adjust the rate-dependent parameter or set the device to automatic settings, using **SETTING** (see “SETTING” on page 42).

After 10 seconds, if no adjustments are made, the message will disappear, the lower screen will remain blank, and the device will continue operating at the selected values.

UPPER RATE vs. SAV and PVARP

WARNING

Pacemaker block point reached.

Adjust RATE or parameters on Menu 2.

The total atrial refractory period (TARP), which is SAV Interval + **PVARP**, cannot be longer than the Upper Rate Interval, or the device will reach the 2:1 block point before being limited by the **UPPER RATE**. This condition is prevented by the following formula:

SAV Interval + **PVARP** < **UPPER RATE** Interval

During manual adjustment of **RATE**, or the rate-dependent parameters, the device will limit adjustment at the block point and display the warning message to the left.

Minimum V-A interval

WARNING

Pacemaker block point reached.

Adjust RATE or parameters on Menu 2.

The minimum V-A interval required by the Model 5388 when operating in DOO mode is 70 ms. This condition is preserved using the following formula:

A-V INTERVAL + 70 ms ≤ **RATE** Interval

The minimum V-A interval required by the Model 5388 when operating in DVI mode is 180 ms. This condition is preserved using the following formula:

A-V INTERVAL + 180 ms ≤ **RATE** Interval

During manual adjustment of **RATE**, or the rate-dependent parameters, the device will limit adjustment at the block point and display the warning message to the left.

Note: This limit only occurs in DVI or DOO mode. In DDD and DDI modes the **RATE** vs. **A-V INTERVAL** and **PVARP** block point maintains the 180 ms minimum.

RATE versus A-V INTERVAL and PVARP

WARNING

Pacemaker block point reached.

Adjust RATE or parameters on Menu 2.

A window must be provided in dual-chamber modes for atrial sensing. The formula used to allow for this window is:

A-V INTERVAL + **PVARP** + 30 ms ≤ **RATE** Interval

If the **RATE** is increased after the rate-dependent parameters have been manually adjusted, the device will limit increase of the **RATE** at the block point and display the warning message to the left.

Turn the **RATE** down, or access Menu **2** and adjust the manually set parameter, or set the device to automatic using **SETTING** (see “SETTING” on page 42).

RATE versus UPPER RATE

The **RATE** and **UPPER RATE** can be set to the same value. However, the **RATE** cannot be set higher than the **UPPER RATE**, nor can the **UPPER RATE** be set lower than the **RATE**.

If the user tries to set the **RATE** above the **UPPER RATE** or vice versa, then the message to the left appears in the lower screen:

WARNING

RATE cannot exceed UPPER RATE.

Adjust RATE or UPPER RATE on Menu 2.

Turn the **RATE** down, or access Menu **2** and increase **UPPER RATE** or set **UPPER RATE** to automatic, using **SETTING** (see “SETTING” on page 42).

Preparation for use 4

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⚠ **Warning:** Properly ground all line-powered equipment used on or in the vicinity of the patient (see “Warnings” on page 14).

△ **Caution:** Monitor the patient’s ECG and blood pressure and keep defibrillation equipment on standby, immediately available for emergency use during pacing lead insertion and pacemaker connection.

Battery Installation

To install (or replace) the battery, press the battery drawer release button until the battery drawer opens (see Figure 4-1). Remove the old battery and replace it with a new 9-Volt type 6LR61 or type 6F22E, or NEDA 1604A (Eveready 522 or equivalent) alkaline battery or a NEDA 1604LC (Ultralife U9VL or equivalent) lithium battery. **Make sure the drawer clicks shut.**

Note: Use of other than the recommended batteries may result in one of the following conditions: (1) less than 24 hours of operation after the low-battery indicator comes on, (2) degraded pacemaker performance, and/or (3) overall reduced battery life.

△ **Caution:** Use of batteries with different physical dimensions from that of the recommended batteries, or use of batteries with contamination on the battery terminals, may result in erratic, or no, pacing output.

Note: Medtronic does not recommend replacing the battery while the pacemaker is turned on.

Note: The battery should be removed when the device is not in use.

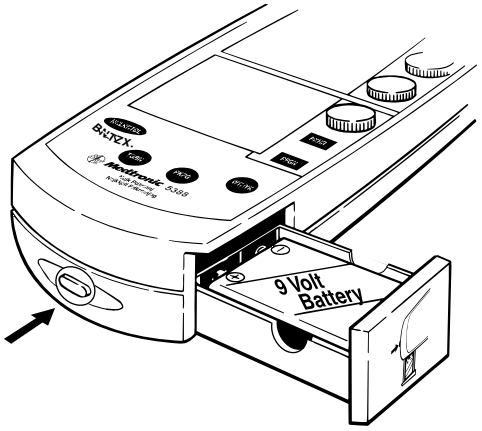


Figure 4-1. Press battery drawer release button.

Disposable Pouch

Description

The Model 5409 Disposable Pouch is designed to protect and hold the Model 5388 Temporary Pacemaker. The pouch consists of a see-through plastic pocket mounted on an attachment panel. The pouch should be disposed of after one patient use. The pouch can be hung from an IV stand.

Procedure for Use

Insert the temporary pacemaker into the pouch, bottom end first, with the front of the pacemaker facing away from the attachment panel. Fold the flip-over top over itself to secure the temporary pacemaker in the pouch. Insert the patient cable connector plugs through the slits in the pouch and insert them into the temporary pacemaker.

Note: To prevent accidental changes of pacemaker controls, do not place the Model 5388 Temporary Pacemaker in any area outside of direct observation by medical staff. The temporary pacemaker should be placed in an area that minimizes access to device controls by unauthorized personnel, such as patients or visitors.

Disposable Cover

Description

The Model 5441 Disposable Cover is designed to prevent unathorized access to the controls of the Model 5388 Temporary Pacemaker. The cover consists of rigid see-through plastic. The cover should be disposed of after one patient use.

△ **Caution:** Use of the cover will prevent direct access to the Model 5388 emergency key. The Model 5388 should be used only according to labeling, and safe handling should still be observed even when the cover is used.

Cables

Medtronic Models 5433A and 5433V Patient Cables

The Patient Cable Models 5433A and 5433V are designed to connect atrial and ventricular pacing lead systems to the Medtronic Model 5388 Temporary Pacemaker for temporary, external pacing.

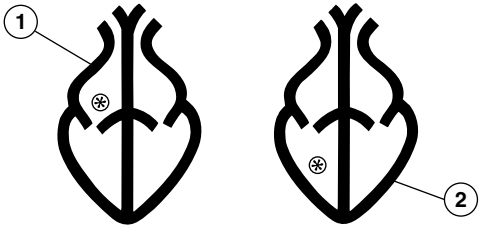
The Patient Cable Models 5433A and 5433V have recessed, non-exposed pins. They are reusable, supplied non-sterile, and should be sterilized prior to use, using either steam (reliable up to 25 autoclave cycles) or ethylene oxide (see “Sterilization” on page 97).

The lead connector assembly at one end of each cable accepts endocardial or myocardial pacing lead connector pins 0.38 mm to 2.41 mm (0.015 inch to 0.095 inch) in diameter. The terminal connector at the other end of each cable is designed to mate with the output terminal on the Model 5388 pacemaker.

Do not expose the cables to storage temperatures above 66°C (150°F) or below -40°C (-40°F).

The two cables are identical except for color coding and markings:

- The Model 5433A, for atrial use, has a blue connector block and blue band around the terminal pin block. One side of the connector block carries a symbol denoting Atrial Use (see Figure 4-2.1).
- The Model 5433V, for ventricular use, has a white connector block and white band. One side of the connector block carries a symbol denoting Ventricular Use (see Figure 4-2.2).



1 Atrial Use
2 Ventricular Use

Figure 4-2. The Model 5433A Atrial Use symbol and the Model 5433V Ventricular Use symbol.

Connector Setup

Connecting or disconnecting the Model 5433A or 5433V Patient Cable to or from the Model 5388

⚠ **Warning:** Connect the patient cable to the temporary pacemaker before connecting the leads to the patient cable.

△ **Caution:** Do not hang the Model 5388 by the cables. The attachment ring or bails should be used when mechanical support of the pacemaker is necessary.

Notes:

- The Patient Cable Models 5433A and 5433V are supplied non-sterile. They should be cleaned and sterilized according to the instructions in Chapter 6 (see “Cleaning” on page 96).
- Carefully inspect the patient cable for visible signs of wear or damage.

To connect the cable to the Model 5388:

With the Model 5388 pacemaker turned off, fully insert the appropriate (atrial or ventricular) patient cable connector plug into the appropriate Model 5388 connector receptacle (marked “A” or “V”) until it **“clicks”** (see Figure 4-3).

Note: The **click** verifies that the plug is completely inserted into the receptacle. Pull **gently** on the plug after insertion to ensure a good connection.

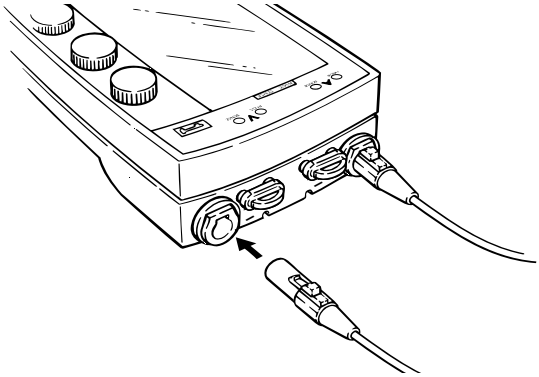


Figure 4-3. Connecting the Model 5433A or 5433V Patient Cable to the Model 5388 Temporary Pacemaker.

To disconnect the cable from the Model 5388:

1. To disconnect the patient cable from the device, press the connector release button on the patient cable plug (see Figure 4-4).

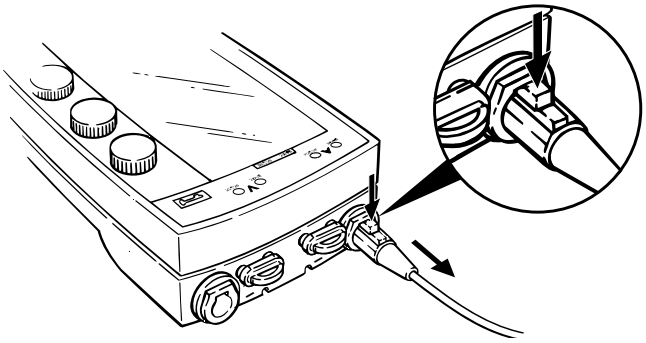


Figure 4-4. Disconnecting the Model 5433A or Model 5433V Patient Cable from the Model 5388 Temporary Pacemaker.

2. Gently pull the plug from the receptacle.

△ **Caution:** It is important to keep hands and gloves free of blood and body fluids while connecting or disconnecting the Model 5433A or 5433V patient cable and/or pacing leads to the Model 5388 pacemaker to avoid contaminating difficult to clean areas.

Connecting the Pacing Lead System to the Model 5433A or 5433V Patient Cable

Note: Carefully inspect the leads for visible signs of wear or damage.

1. Loosen the patient cable connector knobs by twisting each knob counterclockwise until resistance is felt.
2. Insert the lead connector pins into the patient cable receptacles as shown (see Figure 4-5). It is important to connect each lead system to the appropriate patient cable (atrial or ventricular).

   For bipolar systems – Insert each connector pin into the appropriate receptacle (marked + and –). Bipolar lead systems may exhibit different threshold values depending on the polarity of the lead connections.

3. Finger tighten each terminal knob clockwise until snug. Gently pull on each lead conductor to verify a secure connection.

△ **Caution:** Bipolar lead systems are recommended over unipolar systems because they are less susceptible to electromagnetic interference (see "Bipolar Lead Systems" and "Unipolar Lead Systems" on page 17).

For unipolar systems –
One lead system (single chamber) – Insert the cardiac lead connector pin into the negative (–) receptacle of the cable. Insert the connector pin of the "indifferent" electrode (or "ground") into the positive (+) receptacle of the cable.

Two lead systems (dual chamber) – Insert the connector pin of each cardiac lead into the negative (–) receptacle of the appropriate cable. Insert the connector pin of the indifferent electrode into the positive (+) receptacle of one patient cable. Then connect the indifferent electrode to the positive receptacle of the other patient cable, using a jumper cable.

Note: Failure to use a jumper cable will result in no pacing or sensing in the chamber not jumpered to the indifferent electrode.

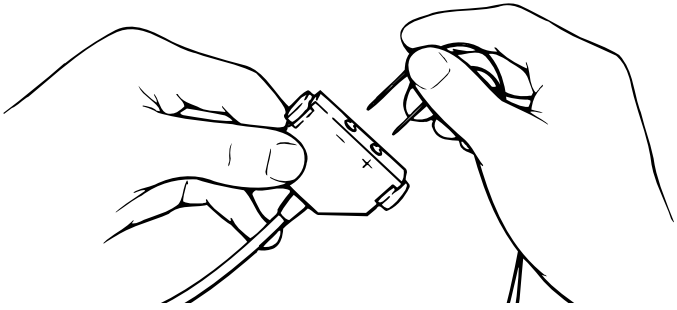


Figure 4-5. Connecting the pacing lead system to the Model 5433A or 5433V Patient Cable receptacles.

Connecting the Pacing Lead System Directly to the Model 5388 Pacemaker

⚠ **Warning:** Do not connect heartwires or leads directly to the Model 5388 except in emergency situations.

△ **Caution:** There is no locking mechanism within the connector pin receptacles to hold connector pins securely in place; consequently, use the Model 5433A or 5433V patient cable whenever possible (see “Connecting the Pacing Lead System to the Model 5433A or 5433V Patient Cable” on page 60).

△ **Caution:** The connector pins must be at least 12.67 mm (0.5 inches) in length.

△ **Caution:** It is recommended that exposed pins and wires be covered to prevent contact with each other, or with electrically conductive or wet surfaces.

1. Remove each connector pin receptacle seal by gripping the rubber handle and pulling it away from the device.

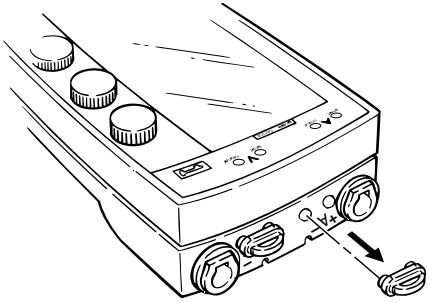


Figure 4-6. Removing the connector pin receptacle seals.

2. Push the connector pins into the holes on the connector block as shown (see Figure 4-7).

   △ **Caution:** DO NOT insert the pins into the receptacle for the patient cable.

   For bipolar systems – Insert each pin into the proper receptacle (marked + and –) of the appropriate chamber (marked “A” or “V”). Bipolar lead systems may exhibit different threshold values depending on the polarity of the lead connections.

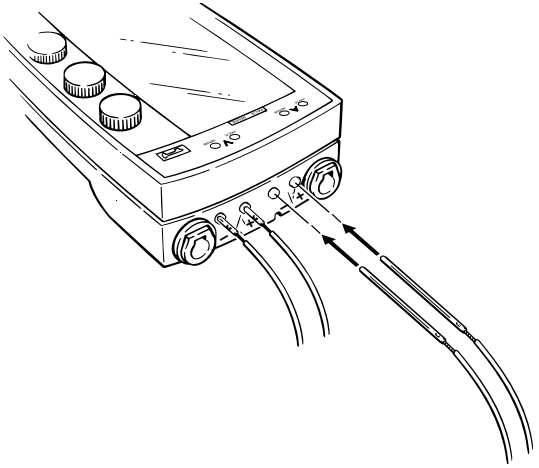


Figure 4-7. Connecting connector pins directly to the Model 5388.

△ **Caution:** Bipolar lead systems are recommended over unipolar systems because they are less susceptible to electromagnetic interference (see “Bipolar Lead Systems” and “Unipolar Lead Systems” on page 17).

3. To remove the pins, simply pull them out.

△ **Caution:** It is important to keep hands and gloves free of blood and body fluids while connecting or disconnecting the temporary pacing leads to the Model 5388 pacemaker to avoid contaminating difficult to clean areas.

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Overview

Features

- **Single chamber pacing** – AOO, VOO, AAI, VVI
- **Dual chamber pacing** – DDD, DDI, DVI, DOO
- **Easy-to-view rate and output settings**
- **Easy-to-view setup indicators** – show in which chamber(s) the device is set to pace and/or sense.
- **Pace and sense indicators** – show pacemaker interaction with the heart
- **Low battery indicator** – indicates when to replace the battery
- **Three dial operation** – provides therapy for most patient needs
- **Rate-dependent parameters** – rate adjustment automatically sets Upper Rate, PVARP, and A-V Interval
- **LOCK/UNLOCK key** – safeguards against unintentional parameter changes
- **Lower screen messages** – aid in device operation
- **Menu screens** – for adjusting additional parameters, including sensitivity, rate-dependent parameters; for RAP (Rapid Atrial Pacing); and for directly selecting four modes: DDD, DVI, DOO and VVI
- **PAUSE key** – suspends pacing and sensing so patient's intrinsic rhythm can be viewed
- **EMERGENCY key** – starts dual chamber asynchronous (DOO) pacing at maximum output

What is Dual Chamber Pacing?

A pacemaker is able to sense the heart's electrical activity and determine if it is necessary to stimulate the heart to contract or "beat". A dual chamber pacemaker has the ability to sense and pace in both chambers of the heart – the atrium and the ventricle.

The Medtronic Model 5388 Temporary Pacemaker is a dual chamber temporary pacemaker. When first turned on, it senses the heart's intrinsic activity. If it senses normal contractions in the atrium or ventricle, pacing is inhibited. If it senses no intrinsic activity in a chamber, pacing occurs in that chamber.

Indicators

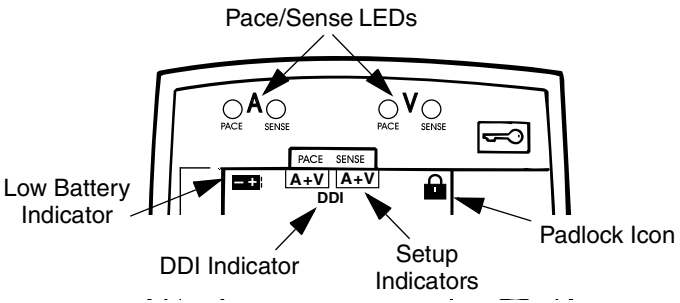


Figure 5-1. Indicators.

Pace/Sense LEDs

One set of pace/sense LEDs is for the atrium; the other for the ventricle. The green pace LED flashes each time the device delivers a pacing stimulus. The orange sense LED flashes each time the device senses the patient's heartbeat.

Setup Indicators

The setup indicators identify in which chamber(s) the device is setup to pace and in which chamber(s) the device is setup to sense |**A**|, |**V**|, or |**A+V**|.

Low Battery Indicator

When the battery voltage is low, the low battery indicator appears and the backlights do not turn on.

When the low battery indicator appears during device operation, the battery should be replaced as soon as possible. (The device operates adequately for approximately 24 hours after the low battery indicator first appears.)

DDI Indicator

This indicator appears while the device is pacing in the DDI mode. When the device is in DDD mode (dual chamber pacing and sensing), manually turning off **A** (Atrial) **TRACKING** changes the mode to DDI.

Lock Indicator

The padlock icon appears when the three upper dials are locked, indicating that **RATE** and **OUTPUT** cannot be adjusted. If you turn the **RATE**, **A OUTPUT**, or **V OUTPUT** dial, the upper screen displays another padlock symbol along with a flashing key symbol. The lower screen displays a message that tells you how to unlock the upper dials for **RATE** and **OUTPUT**.

Basic Operation

On/Off

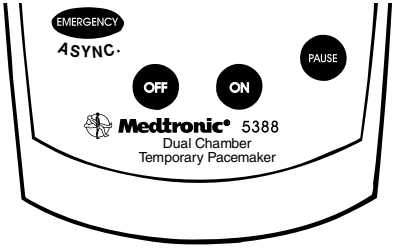


Figure 5-2. On/Off.

When you press the **ON** key, the pacemaker performs a power-on self-test that lasts about four seconds.

- If the battery voltage is low, the battery indicator appears and the backlights do not turn on.
- If the device fails the self-test, the device remains on but does not pace.
- If the device passes the self-test, the upper and lower screens initialize, the backlights turn on, and dual chamber pacing and sensing begin at these nominal values:

Table 5-1. Nominal Values at Power-On.

RATE	80 min^{-1}	**A-V INTERVAL**	170 ms
A OUTPUT	10 mA	**A SENSITIVITY**	0.5 mV
V OUTPUT	10 mA	**V SENSITIVITY**	2.0 mV
UPPER RATE	110 min^{-1}		

Note: During the self-test, information in the display buffer from the previous use of the device will appear on the upper display. This information is cleared during screen initialization and nominal values are restored.

To Turn Device On

Press the **ON** key.

Note: Pressing the **EMERGENCY** key also turns the device on.

To Turn Device Off

Press the **OFF** key twice within five seconds.

Note: After you press **OFF** the first time, the following message appears on the lower screen as a reminder to press the **OFF** key a second time within five seconds.

Figure 5-3. Device Shut-Down Message.

Emergency Pacing

When you press the **EMERGENCY** key, the pacemaker initiates high output dual chamber asynchronous pacing, whether the pacemaker is on or off. Pacing occurs at these parameter values:

Table 5-2. Emergency Pacing Values.

RATE	Current setting (or 80 min^{-1}) if device is off when **EMERGENCY** key is pressed)	**A-V INTERVAL**	Current setting (or 170 ms if device is off when **EMERGENCY** key is pressed)
A OUTPUT	20 mA	**A SENSITIVITY**	ASYNC.
V OUTPUT	25 mA	**V SENSITIVITY**	ASYNC.

To Initiate Emergency Pacing

Press the **EMERGENCY** key (device may be on or off).

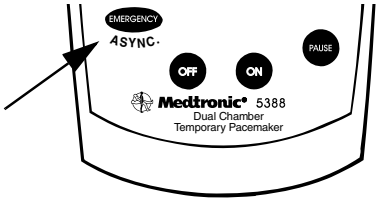


Figure 5-4. Emergency.

To Terminate Emergency Pacing

Press the **ON** key to resume dual chamber demand (synchronous) pacing:

- **RATE**, **A OUTPUT**, and **V OUTPUT** will remain at the values displayed at the time that **ON** is pressed.
- **A SENSITIVITY** and **V SENSITIVITY** will return to the nominal values.

  Note: Regardless of which mode the device was operating in before Emergency pacing, pressing the **ON** key during Emergency, DOO mode, pacing sets the device to DDD mode pacing. If necessary, adjust the parameters to set the device to a different mode.

Lock/Unlock

The **LOCK/UNLOCK** key locks and unlocks the three upper dials. When the upper dials are locked, the padlock icon appears and the rate, atrial output, and ventricular output cannot be adjusted. Also, the screen backlight is turned off.

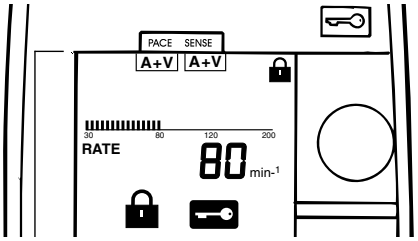


Figure 5-5. Lock/Unlock.

Press the **LOCK/UNLOCK** key to unlock the upper dials before adjusting rate or output.

Press the **LOCK/UNLOCK** key to lock the upper dials after adjusting rate, output, and other pacing parameters.

Notes:

- To prevent unintentional parameter changes, the upper dials automatically lock 60 seconds after the last parameter adjustment.
- The **ON**, **OFF**, **MENU**, **EMERGENCY**, and **PAUSE** keys also unlock the Model 5388 and allow the upper dials to function.
- The lock icon and flashing key icon appear in the middle of the screen if dials are turned while the upper screen is locked.

Viewing the Patient's Intrinsic Rhythm

The recommended method for viewing the patient's intrinsic rhythm is to reduce the pacing rate. Another option, however, is to use the **PAUSE** key.

To Pause

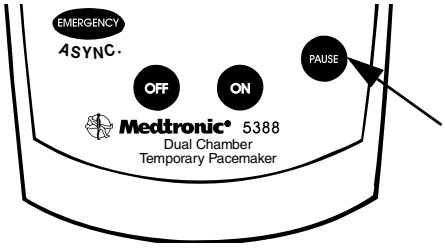


Figure 5-6. Pause.

Press and hold the **PAUSE** key.

Pacing and sensing are suspended for ten seconds unless you release the **PAUSE** key sooner.

Note: To pause up to ten seconds again, release the **PAUSE** key; then press and hold the **PAUSE** key again. (This is a safety feature.)

Rate and Output Adjustments

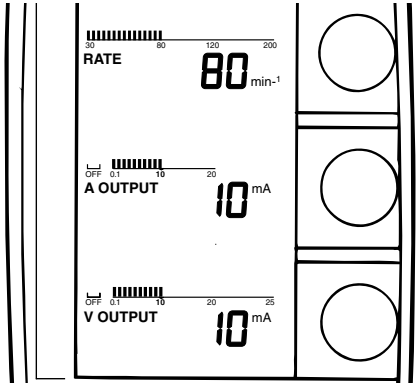


Figure 5-7. Rate and Output.

The upper dials are used to adjust the pacing rate (min^{-1}), atrial output (mA), and ventricular output (mA). The upper screen displays a numerical value and segmented line graph that reflects the current setting for each dial.

To Adjust Rate

Turn the **RATE** dial clockwise to increase the rate; counterclockwise to decrease the rate.

Rate range: 30 min^{-1} to 200 min^{-1}

Note: When the rate is set higher than 120 min^{-1}, the bar size on the segmented line graph gets taller and thicker.

To Adjust Atrial Output

Turn the **A OUTPUT** dial clockwise to increase atrial output; counterclockwise to decrease atrial output or set to **OFF**.

Atrial output range: 0.1 mA to 20 mA

To Adjust Ventricular Output

Turn the **V OUTPUT** dial clockwise to increase ventricular output; counterclockwise to decrease ventricular output or set to **OFF**.

Ventricular output range: 0.1 mA to 25 mA

Note: When **V OUTPUT** is set higher than 20 mA, the bar size on the segmented line graph gets taller and thicker and the HIGH OUTPUT icon appears.

Demand Pacing

During demand (synchronous) pacing, output is inhibited when the pacemaker senses intrinsic activity. This minimizes competition between the paced rhythm and the intrinsic activity of the heart.

Note: Be sure to determine sensitivity thresholds (see page 81), or asychronous pacing may occur.

When the device is off, pressing the **ON** key immediately initiates dual chamber demand pacing. To quickly change from dual chamber to single chamber demand pacing, set either **A OUTPUT** or **V OUTPUT** to **OFF**.

To Set To Dual Chamber Demand Pacing

1. Check the Setup Indicators. If they are |**A+V**||**A+V**| , skip to step 3, as the device is already setup to pace and sense in both chambers.
2. Turn **A OUTPUT** and **V OUTPUT** on.

   If sensing is off in both chambers, press **ON** twice to resume dual chamber demand pacing.

   Pacing and sensing occurs in both chambers.
   A SENSITIVITY is 0.5 mV*, and* **V SENSITIVITY** is 2.0 mV.

   If sensing is off in only one chamber, refer to “Sensitivity” on page 78.
3. Turn the **A OUTPUT** and **V OUTPUT** dials to adjust output to appropriate values.

Resulting Setup Indicators: |**A+V**||**A+V**|

To Set To Demand Pacing In The Atrium

1. Verify the Setup Indicators are |**A+V**||**A+V**| . These indicate the device is setup to pace and sense in both chambers.

2. Turn the **V OUTPUT** dial counterclockwise until **OFF** is highlighted.

   Pacing and sensing occur only in the atrium.

Resulting Setup Indicators: |**A** | **A** |

To Set To Demand Pacing In The Ventricle

1. Verify the Setup Indicators are |**A+V**| |**A+V**| . These indicate the device is setup to pace and sense in both chambers.
2. Turn the **A OUTPUT** dial counterclockwise until **OFF** is highlighted.

   Pacing and sensing occur only in the ventricle.

Resulting Setup Indicators: | **V**| | **V**|

Note: When **A OUTPUT** or **V OUTPUT** is turned back on, sensitivity returns to the nominal value.

Asynchronous Pacing

Patients best suited for asynchronous (non-sensing) modes have:

- An intrinsic rate consistently below the pacing rate.

  – or –

- No intrinsic activity.

△ **Caution:** Because it may compete with the intrinsic activity of the heart, asynchronous pacing may result in tachyarrhythmia. Use caution when setting the device to asynchronous modes.

Pressing the **EMERGENCY** key immediately initiates dual chamber asynchronous pacing. To quickly set the device to single chamber asynchronous pacing, press the **EMERGENCY** key and turn either **A OUTPUT** or **V OUTPUT** to **OFF**.

To Set To Dual Chamber Asynchronous Pacing

1. Press the **EMERGENCY** key.

   The ASYNCHRONOUS PACING message appears.

2. Adjust **A OUTPUT** and **V OUTPUT** to provide adequate safety margins to assure capture.

   Pacing occurs in the atrium and ventricle. No sensing occurs.

Resulting Setup Indicators: |**A+V**| |

To Set To Asynchronous Pacing In The Atrium

1. Press the **EMERGENCY** key.

   The ASYNCHRONOUS PACING message appears.
2. Turn the **V OUTPUT** dial counterclockwise until **OFF** is highlighted.

   Pacing occurs only in the atrium. No sensing occurs.
3. Adjust **A OUTPUT** to provide an adequate safety margin.

Resulting Setup Indicators: |**A** | |

To Set To Asynchronous Pacing In The Ventricle

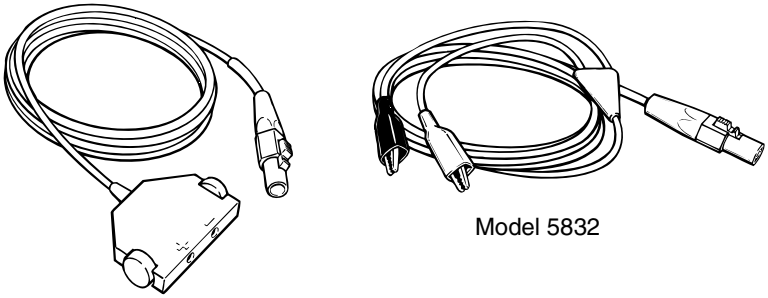
1. Press the **EMERGENCY** key.

   The ASYNCHRONOUS PACING message appears.
2. Turn the **A OUTPUT** dial counterclockwise until **OFF** is highlighted.

   Pacing occurs only in the ventricle. No sensing occurs.
3. Adjust **V OUTPUT** to provide an adequate safety margin.

Resulting Setup Indicators: | **V**| |

Connector Setup



Model 5433A/
5433V

Model 5832

Figure 5-8. Cables.

Notes:

- Connect the cable to the temporary pacemaker before connecting the lead system to the cable.

- Do not connect the Model 5388 to the lead system if the Model 5388 is turned on and is operating at an output amplitude that could cause capture.

1. Plug the Model 5433A and Model 5433V patient cables into appropriate sockets at the top end of device (see Figure 5-9).

   – or –

   Plug a pair of Model 5832 or Model 5832S surgical cables into appropriate sockets at the top end of device (see Figure 5-9).

   One socket is marked **A** *(atrium); the other* **V** *(ventricle).*

Note: To disconnect cable from the device, press connector release button on cable and pull gently from socket.

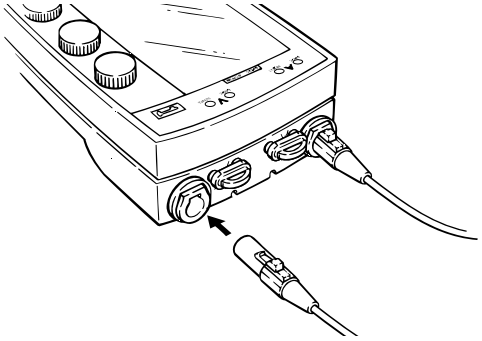


Figure 5-9. Cable to Device Connections.

2. Connect leads/heartwires to the appropriate cable. Match positive (+) and negative (–) leads to positive (+) and negative (–) sockets or clips for the atrium and ventricle (not shown).

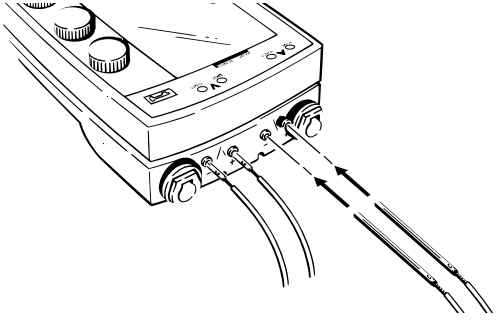


Figure 5-10. Emergency Connections.

In an emergency and in the absence of patient or surgical cables, temporary pacing leads or heartwires plug directly into the four smaller sockets (two for the atrium; two for the ventricle) at the top end of device (see Figure 5-10).

△ **Caution:** These are not the primary connector setup methods because there is no locking mechanism for the connection.

Pacing Parameter Adjustments

Menus allow you to manually adjust pacing parameters. The parameters displayed on menus are based on the currently programmed pacing mode, rate, and output. Parameters not selectable are dimmed (i.e., grayed-out) on the menu screen.

- The **MENU** key activates the lower screen and allows you to page through the four menus listed here (see Figure 5-11):

Menu 1	A Sensitivity/V Sensitivity/A-V Interval/A Tracking
Menu 2	Upper Rate/PVARP/A-V Interval/ SETTING (AUTO-MANUAL)
Menu 3	Rapid Atrial Pacing (RAP)
Menu M	Dial-a-Mode

- The **SELECT** key allows you to scroll through and select parameters displayed on each menu.
- The **MENU PARAMETER** dial allows you to adjust the value of the selected parameter.

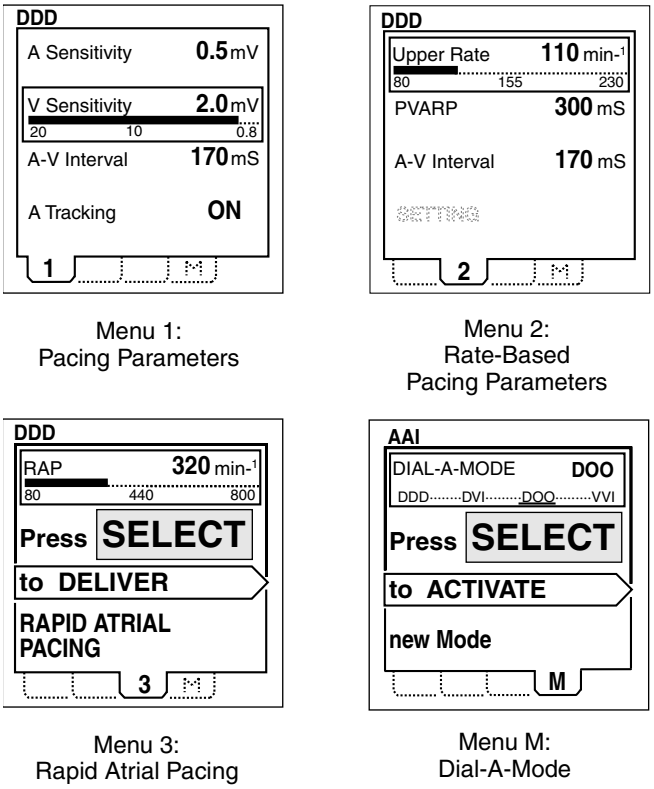


Figure 5-11. Lower Screen Menus.

Sensitivity

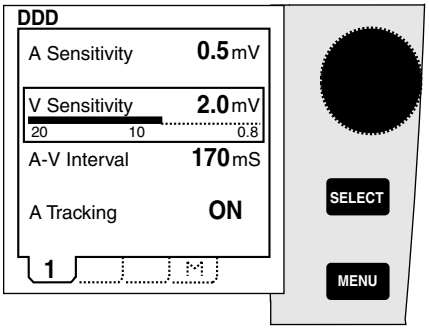


Figure 5-12. Sensitivity.

To Adjust Atrial/Ventricular Sensitivity

1. Press the **MENU** key until Menu 1 is displayed.
2. Press the **SELECT** key until **A SENSITIVITY** or **V SENSITIVITY** is highlighted.
3. Turn the **MENU PARAMETER** dial clockwise to increase sensitivity (decrease numerical value); counterclockwise to decrease sensitivity (increase numerical value). Turn the dial all the way counterclockwise to reach ASYNC (no-sensing).

Atrial sensitivity range: 0.4 mV - 10 mV and **ASYNC.**

Ventricular sensitivity range: 0.8 mV - 20 mV and A**SYNC.**

Notes:

- Setting **A SENSITIVITY** to **ASYNC** turns atrial sensing off and starts asynchronous pacing in the atrium.
- Setting **V SENSITIVITY** to **ASYNC** turns ventricular sensing off and starts asynchronous pacing in the ventricle.
- The highest number (in mV) for **A SENSITIVITY** or **V SENSITIVITY** is the least sensitive setting; the lowest number (in mV) is the most sensitive setting.
- **A SENSITIVITY** and **V SENSITIVITY** are not selectable (grayed-out) if the corresponding **A OUTPUT** or **V OUTPUT** is **OFF**.

Rate-Dependent Parameters

UPPER RATE, **PVARP**, and **A-V INTERVAL** are automatically set whenever **RATE** is adjusted, or can be manually adjusted from Menu 2. Adjusting **RATE** does not change the **UPPER RATE**, **PVARP**, or **A-V INTERVAL** if these values were manually adjusted from Menu 2.

To Adjust Upper Rate

1. Press the **MENU** key until Menu 2 is displayed.
2. Press the **SELECT** key until **UPPER RATE** is highlighted.
3. Turn the **MENU PARAMETER** dial clockwise to increase the upper rate; counterclockwise to decrease the upper rate.

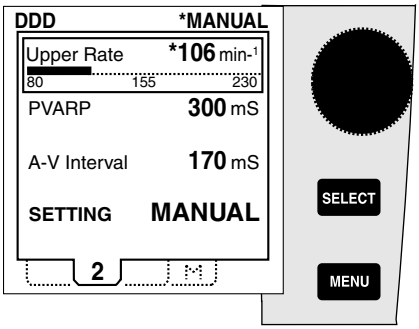


Figure 5-13. Upper Rate.

To Adjust PVARP

1. Press the **MENU** key until Menu 2 is displayed.
2. Press the **SELECT** key until **PVARP** is highlighted.
3. Turn the **MENU PARAMETER** dial clockwise to lengthen the **PVARP**; counterclockwise to shorten the **PVARP**.

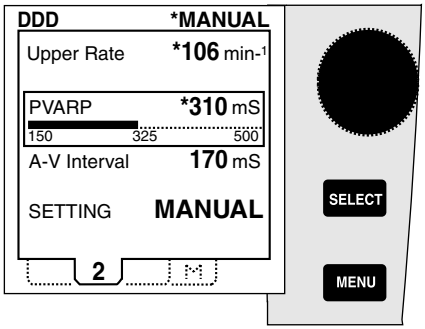


Figure 5-14. PVARP.

To Adjust A-V Interval

1. Press the **MENU** key until Menu 1 or 2 is displayed.
2. Press the **SELECT** key until **A-V INTERVAL** is highlighted.
3. Turn the **MENU PARAMETER** dial clockwise to lengthen the **A-V INTERVAL**; counterclockwise to shorten the **A-V INTERVAL**.

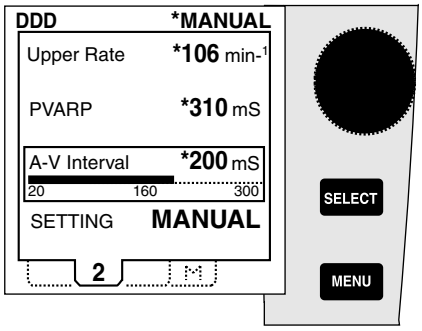


Figure 5-15. A-V Interval.

To Reset Rate-Dependent Values To Automatic Settings

1. Press the **MENU** key until Menu 2 is displayed.
2. Press the **SELECT** key until **SETTING** is highlighted.
3. Turn the **MENU PARAMETER** dial clockwise to display **AUTO**.

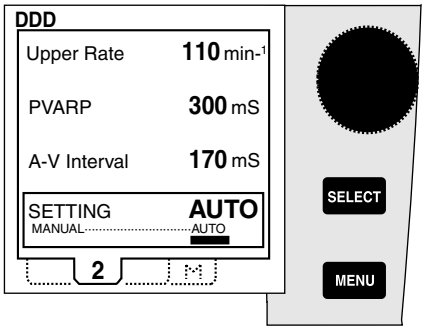


Figure 5-16. Resetting to Automatic Values.

Thresholds

Threshold values are needed to determine the appropriate settings for output and sensitivity. Procedures for finding atrial and ventricular sensing and stimulation thresholds are presented in this section.

Note: To reduce the risk of competitive pacing, find the sensing thresholds first (if the patient's intrinsic rhythm is adequate).

Sensing Definitions

The ECG below shows intrinsic beats mixed with paced beats. The pacemaker detects the heart's own beat and does not deliver a pacing stimulus.

Figure 5-17. Sensing.

The ECG below shows one example of undersensing. The pacemaker does not detect intrinsic activity and thus paces on or between beats.

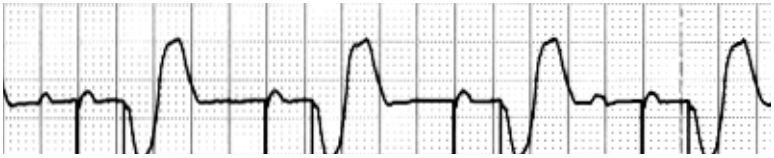


Figure 5-18. Atrial Undersensing.

Sensing Threshold

The sensing threshold is the least sensitive setting at which the pacemaker can detect a heartbeat. Monitor the patient's ECG and blood pressure as you follow the procedure to find the atrial and ventricular sensing thresholds.

Safety Margin

Lead maturation and drug therapy can affect the threshold. To ensure sensing and accommodate a changing threshold, it is important to provide at least a 2:1 safety margin. Set **A SENSITIVITY/V SENSITIVITY** to a value that is at least one-half to one-third the sensing threshold value. For example, an appropriate setting for a patient with a 5.0 mV sensing threshold is 2.5 mV or less.

To Find Atrial or Ventricular Sensing Thresholds

Caution: Pacing-dependent patients will have limited or no intrinsic rate/rhythm. This procedure should be used only on patients with adequate intrinsic rhythm.

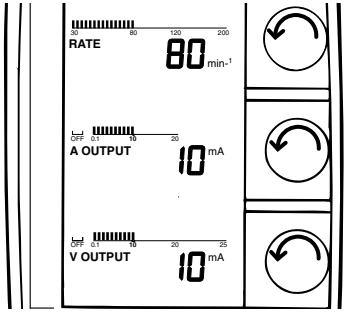


Figure 5-19. Decrease Rate and Output.

1. Turn on the temporary pacemaker without connecting it to the patient lead system.

   Caution: Do not connect the temporary pacemaker to the patient lead system before step 4.
2. Set **RATE** at least 10 min^{-1} below patient's intrinsic rate.

   This adjustment ensures non-pacing.
3. **Atrial:** Set **A OUTPUT** to 0.1 mA.

   – or –

   Ventricular: Set **V OUTPUT** to 0.1 mA.

   This adjustment prevents the risk of competitive pacing.
4. Connect the temporary pacemaker to the patient lead system.
5. Press the **MENU** key until Menu **1** is displayed.
6. **Atrial: A SENSITIVITY** is highlighted.

   – or –

   Ventricular: Press the **SELECT** key to highlight **V SENSITIVITY**.

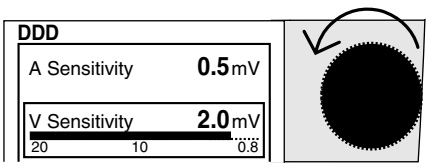


Figure 5-20. Decrease Sensitivity.

7. Decrease **SENSITIVITY**: Slowly turn the **MENU PARAMETER** dial counterclockwise (increase mV value) until the sense indicator stops flashing.

   The pace indicator flashes continuously, but capture is not likely because the output value is at minimum.

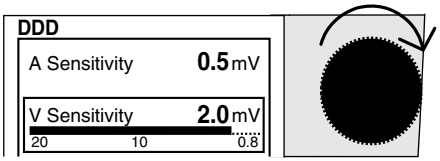


Figure 5-21. Increase Sensitivity.

8. Increase **SENSITIVITY**: Slowly turn the **MENU PARAMETER** dial clockwise (decrease mV value) until the sense indicator starts flashing.

   The pace indicator stops flashing.

   This value is the sensing threshold.

9. Set **SENSITIVITY** to half (or less) the threshold value.

   This setting provides at least a 2:1 safety margin.

10. Restore **RATE**, **A OUTPUT**, or **V OUTPUT** to previous values.

Capture Definitions

When a pacing pulse captures the heart, it causes the heart to beat – that is, contract and pump blood. The ECG shows a P-wave or QRS complex after the pulse, as in the example shown here:

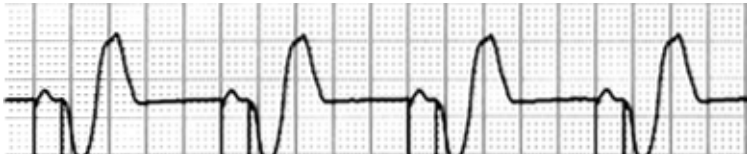


Figure 5-22. Capture.

When capture is lost, the ECG shows no heart response after the pulse, as in the example shown here:

Figure 5-23. Loss of Ventricular Capture.

Stimulation Threshold

The stimulation threshold is the minimum output (mA) needed to consistently capture the heart. Monitor the patient's ECG and blood pressure as you follow the procedure to find the atrial and ventricular stimulation thresholds.

Safety Margin

Lead maturation and drug therapy can affect the threshold. To achieve consistent capture and accommodate a changing threshold, it is important to provide at least a 2:1 safety margin. Set **A OUTPUT/V OUTPUT** to a value at least 2 to 3 times greater than the stimulation threshold value. For example, the appropriate output setting for a patient with a 1.0 mA threshold is 2.0 mA or greater.

To Find Atrial or Ventricular Stimulation Thresholds

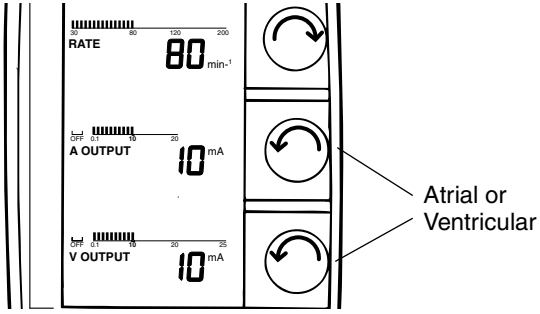


Figure 5-24. Increase Rate, Decrease Output.

1. Patient is connected to temporary pacemaker and is being monitored on ECG.
2. Set **RATE** at least 10 min^{-1} above patient's intrinsic rate.

   This adjustment ensures pacing. The pace indicator flashes.

3. Decrease **OUTPUT**: Slowly turn the **OUTPUT** dial counterclockwise until ECG shows loss of capture.

   Pace and sense indicators flash intermittently.

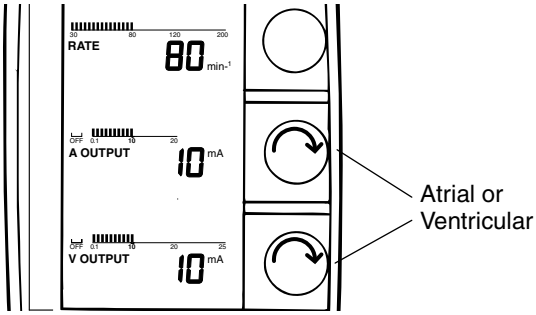


Figure 5-25. Increase Output.

4. Increase **OUTPUT**: Slowly turn the output dial clockwise until ECG shows consistent capture.

   The pace indicator flashes continuously; the sense indicator stops flashing.

   This value is the stimulation threshold.

5. Set **OUTPUT** to a value at least 2 to 3 times greater than the stimulation threshold value.

   This setting provides at least a 2:1 safety margin.

6. Restore **RATE** to previous value.

Pacing Setup

The Medtronic Model 5388 Temporary Pacemaker can be set to a single chamber mode (AOO, VOO, AAI, VVI) or a dual chamber mode (DDD, DDI, DVI, DOO).

To quickly set the device to the desired pacing mode, adjust **OUTPUT** (upper dials), **SENSITIVITY** (Menu 1), and/or **A** (Atrial) **TRACKING** (Menu 1).

The Pacing Setup Table (see page 92) provides a quick reference for selecting a pacing mode. Refer to “Basic Operation” (see page 68) and “Pacing Parameter Adjustments” (see page 77) for step-by-step instructions on how to adjust output and sensitivity.

Atrial Tracking

To change from DDD to DDI mode, set **A TRACKING** to **OFF** (from Menu 1). Conversely, to change from DDI to DDD mode, set **A TRACKING** to **ON** (from Menu 1).

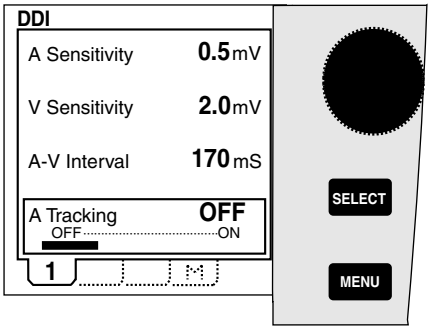


Figure 5-26. Atrial Tracking.

To Turn Atrial Tracking Off or On

1. Press the **MENU** key until Menu 1 is displayed.
2. Press the **SELECT** key until **A TRACKING** is highlighted.
3. DDI mode: Turn the **MENU PARAMETER** dial counterclockwise to display **OFF**.

   DDI pacing and sensing begin. The DDI indicator appears.

   DDD mode: Turn the **MENU PARAMETER** dial clockwise to display **ON**.

   DDD pacing and sensing begin.

Note: A TRACKING can be set to **OFF** only from DDD mode and set to **ON** only from DDI mode.

Dial-A-Mode

Menu M allows you to select DDD, DOO, DVI, or VVI pacing modes.

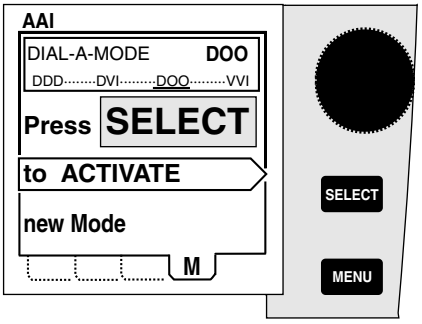


Figure 5-27. Dial-A-Mode.

To Dial-a-Mode

1. Press the **MENU** key until Menu M is displayed.
2. Turn the **MENU PARAMETER** dial to underline desired pacing mode.
3. Press the **SELECT** key to activate the selected pacing mode.

Pacing in the selected mode begins as follows:

- Manually set values for **UPPER RATE**, **PVARP**, and **A-V INTERVAL** are retained when they apply to the newly selected mode. Otherwise, the settings are returned to their automatic, rate-dependent values.

  Example: If you change from DVI to DDD mode, the setting for **A-V INTERVAL** is retained or "carried forward". **UPPER RATE** and **PVARP** are set to their automatic, rate-dependent values.
- Nominal or previously programmed settings for **OUTPUT** and **SENSITIVITY**.

  Example: If you change from AAI to DDD mode, the value for **A OUTPUT** is retained; **V OUTPUT** is set to the nominal value.
- Previously programmed **RATE**.

RAP (Rapid Atrial Pacing)

△ **Caution:** RAP is for atrial use only. Be sure the leads are connected to the atrium, not the ventricle, before enabling RAP.

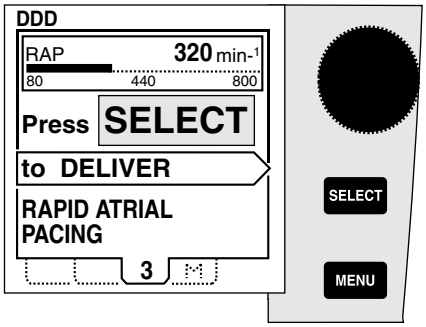


Figure 5-28. RAP (Rapid Atrial Pacing).

To Deliver Rap

1. Verify that the leads are in contact with the atrium and are connected to the atrial channel of the device through a patient or surgical cable.
2. Press the **MENU** key until Menu 3 is displayed.

   *Screen displays RAP rate (initial rate of 320 min^{-1} or rate last set). Pacing continues at currently dis***played settings.**
3. ***Adjust RAP rate as needed: Turn the MENU PARAMETER*** dial clockwise to increase rate; counterclockwise to decrease rate.

   Range: 80 min^{-1} - 800 min^{-1}
4. Press and hold **SELECT** to deliver RAP burst.

   AOO pacing begins at displayed RAP rate and current **A OUTPUT**. *The* **A PACE LED** *flashes during delivery of RAP pulses.*

Note: There is no ventricular support during RAP.

Note: If **A OUTPUT** is set to **OFF** when you press the **SELECT** key, RAP is delivered at 10 mA. **A OUTPUT** returns to the **OFF** setting as soon as you release the **SELECT** key – even if you adjust **A OUTPUT** during RAP delivery.

To Adjust Rate/Atrial Output During RAP Delivery

1. Continue to press and hold the **SELECT** key.
2. Turn the **MENU PARAMETER** dial to adjust RAP rate.
3. Turn the **A OUTPUT** dial to adjust atrial output.

To Resume Pacing at Upper Screen Settings

- Release the **SELECT** key.

△ **Caution:** RAP may result in tachycardia, acceleration of existing tachycardia, or fibrillation. Apply high rates under careful patient monitoring and control. Monitor the patient's ECG and blood pressure, and ensure defibrillation equipment is immediately available.

Battery Replacement

Replace the battery for each new patient. Replace the battery when the low battery indicator appears during device operation (see page 31). Use a fresh 9V alkaline or lithium battery (Ultralife U9VL, Eveready 522, or equivalent).

Check the battery status at least twice daily. Replace alkaline batteries at least once every week when the temporary pacemaker is in continuous use.

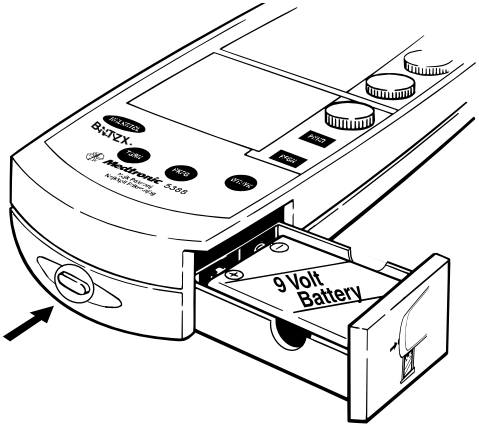


Figure 5-29. Battery Replacement.

To Replace Battery

Note: Medtronic does not recommend replacing the battery while the pacemaker is turned on. However, if during an emergency situation the battery must be replaced while the device is in use, ensure that the device is locked (see "Lock/Unlock Key" on page 24), then replace the battery. Pacing is maintained for 15 seconds, typical, at 70 min^{-1} and nominal outputs (see "Operation After Battery Removal" on page 103).

1. Turn device off.

2. Press button on the bottom of the device to open battery drawer.
3. Remove old battery and discard.
4. Insert fresh battery as shown on the diagram inside the battery drawer.

   Note: Inspect battery terminals for contamination. Use of replacement batteries with contaminated terminals can result in device shutdown.

   Note: The device works with the battery polarity reversed.
5. Close battery drawer. **Make sure it clicks.**

   Note: Failure to fully close the battery drawer can result in the battery drawer opening and the pacemaker shutting down.
6. Press the **ON** key to start power-on self-test.

   The pace/sense and battery indicators flash briefly. If the device passes the power-on self-test, dual chamber demand pacing and sensing begin.

Tables

Table 5-3. Model 5388 Pacing Setup Table.

Setup Indicators	AOO[a]	VOO	AAI	VVI	DOO	DVI	DDD	DDI
	PACE SENSE	PACE SENSE	PACE SENSE	PACE SENSE	PACE SENSE	PACE SENSE	PACE SENSE	PACE SENSE
	A	V	A A	V V	A+V	A+V V	A+V A+V	A+V A+V DDI
Instructions								
1. Set Output								
A Output	On	Off	On	Off	On	On	On	On
V Output	Off	On	Off	On	On	On	On	On
2. Set Sensitivity								
A Sensitivity	ASYNC	NA	On	NA	ASYNC	ASYNC	On	On
V Sensitivity	NA	ASYNC	NA	On	ASYNC	On	On	On
3. Set **A Tracking**	NA	NA	NA	NA	NA	NA	On	Off

[a] **Caution:** DAD and OOO are accessible modes, but are not recommended. Refer to “Controls, Indicators, and Other Features” in the technical manual.

Table 5-4. 3–Letter NBG Pacemaker Code (1987).

X	X	X
Chamber Paced	**Chamber Sensed**	**Sensed Response**
V – Ventricle	V – Ventricle	T – Triggers pacing
A – Atrium	A – Atrium	I – Inhibits pacing
D – Dual (A+V)	D – Dual (A+V)	D – Dual
O – None	O – None	O – None

Table 5-5. Rate and Interval Conversion Chart.

Rate (min^{-1})	Int (ms)	Rate (min^{-1})	Int (ms)	Rate (min^{-1})	Int (ms)
30	2000	100	600	390	154
35	1714	110	545	400	150
40	1500	120	500	410	146
45	1333	130	462	420	143
50	1200	140	429	430	140
52	1154	150	400	440	136
54	1111	160	375	450	133
56	1071	170	353	460	130
58	1034	180	333	470	128
60	1000	190	316	480	125
62	968	200	300	490	122
64	938	210	286	500	120
66	909	220	273	510	118
68	882	230	261	520	115
70	857	240	250	530	113
72	833	250	240	540	111
74	811	260	231	550	109
76	789	270	222	560	107
78	769	280	214	570	105
80	750	290	207	580	103
82	732	300	200	590	102
84	714	310	194	600	100
86	698	320	188	610	98
88	682	330	182	620	97
90	667	340	176	630	95
92	652	350	171	640	94
94	638	360	167	650	92
96	625	370	162		
98	612	380	158		

60,000/ms = min^{-1} or 60,000/min^{-1} = ms

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Cleaning and Sterilization

Model 5388 Temporary Pacemaker

Cleaning

The Model 5388 temporary pacemaker can be cleaned using a sponge or cloth moistened with water or 70% isopropyl alcohol.

Note: Do not expose the unit to ethers, acetone, or chlorinated solvents as these may damage the case or labels.

△ **Caution: The Model 5388 must not be immersed in water or cleaning agents.** Severe damage to the device may occur.

Sterilization

The Model 5388 can be exposed to ethylene oxide gas for disinfection. Due to the variability among sterilizers, precise sterilization instructions must come from the sterilizer manufacturer. However, the process should not exceed temperatures of 52°C (125°F) nor pressures of 103 kPa (15 PSIG). Use an acceptable method such as biological indicators for determining sterilizer effectiveness.

△ **Caution:** Do not sterilize the Model 5388 by gamma irradiation and do not steam-sterilize (autoclave) the device.

Model 5433A and 5433V Patient Cables

The Model 5433A and 5433V Patient Cables are supplied non-sterile, and must be sterilized by steam or ethylene oxide prior to use.

Cleaning

Prior to sterilization, the Model 5433A or 5433V Patient Cable should be cleaned thoroughly with a mild detergent or 70% isopropyl alcohol to remove all visible blood and body fluids. The cables may be immersed for cleaning. The cables must be thoroughly dried after cleaning.

Inspection and testing by a qualified technician should be done after cleaning to verify proper cable function.

Sterilization

Note: While either of the following sterilization methods is acceptable, repeated steam sterilization typically causes more rapid degradation.

Steam Sterilization – Remove the cable from the original package and place the cable in a suitable autoclavable packaging material. The packaged cable should be autoclaved at:

- 121°C (250°F) at 103 kPa (15 PSIG) for 30 minutes, or
- 132°C (270°F) at 186 kPa (27 PSIG) for 7 minutes.

Ethylene Oxide Sterilization – Remove the cable from the original package and wrap the cable in packaging permeable to ethylene oxide. Follow standard method for ethylene oxide sterilization. Use an acceptable method, such as biological indicators, for determining sterilizer effectiveness.

Safety and Technical Checks

Safety and technical checks should be carried out on the Model 5388 at least once every 12 months and after any malfunction or accident. Medtronic recommends that the checks be carried out by qualified engineers and technicians trained in the service of Medtronic products. Below is a brief outline of necessary checks. For service or training contact your Medtronic sales or service representative.

Visual Inspection:

- Technical Manual.
- Inscriptions, information and warning signs properly and completely fixed.
- Mechanical damage to the device.
- Inspection of battery compartment and battery connection for corrosion and other contamination.

Functional Inspection:

- Faultless self-test at power-up.
- Front panel dials, keys, and displays.
- Inspection of all connections and cables.
- Examination of warnings.

Practical Measurements:

- Rate Test
- Rapid Atrial Pacing
- Output
- Sensitivity
- Off Current Drain (150 microamp maximum)
- On Current Drain with backlight and lower screen off (2.95 milliamp max. when measured away from pacing peaks)
- Leakage and Patient Auxiliary Current Measurements per IEC 601-2-31 paragraph 19

△ **Caution:** Do not open the device as this will void the warranty (see the limited warranty on page 106).

Medtronic does not recommend field repair of the device. For service or repair contact your local Medtronic representative at the appropriate address or telephone number listed on the back cover.

Service

Medtronic employs highly trained representatives and engineers located throughout the world to serve you and, upon request, to provide training to qualified hospital personnel in the use of Medtronic products. Medtronic also maintains a professional staff to provide technical consultation to product users. For medical consultation, Medtronic can often refer product users to outside medical consultants with appropriate expertise. For more information, contact your local Medtronic representative, or call or write Medtronic at the appropriate address or telephone number listed on the back cover.

The Medtronic Model 5388 Temporary Pacemaker has been carefully engineered, manufactured and quality tested to provide long, trouble-free service. Should service or repair be necessary, contact your local Medtronic representative at the appropriate address or telephone number listed on the back cover.

A serial number identifying each individual pacemaker is printed on the back surface of the device. This serial number should be referenced in any correspondence regarding this device.

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Medtronic does not recommend replacing the battery while the pacemaker is connected to a patient. 103

Device Specifications

The following specifications apply at 20°C (68°F) ± 2°C (4°F) and with a 500 ohm (± 1%) load.

Modes	AOO, AAI, VOO, VVI, DOO, DDD, DDI, DVI[a]	
Base Rate	30 – 200 min^{-1} ± 5%	30 – 50 min^{-1} in 5 min^{-1} increments 50 – 100 min^{-1} in 2 min^{-1} increments 100 – 200 min^{-1} in 5 min^{-1} increments
Rapid Atrial Pacing Rate	80 – 800 min^{-1} ± 5%	80 – 180 min^{-1} in 20 min^{-1} increments 180 – 250 min^{-1} in 5 min^{-1} increments 250 – 360 min^{-1} in 10 min^{-1} increments 360 – 800 min^{-1} in 20 min^{-1} increments
Output Amplitude		
Atrial	0.1 – 20 mA ± 0.1 mA or 10% (200-1000 Ohms)	0.1 – 0.4 mA in 0.1 mA increments 0.4 – 1.0 mA in 0.2 mA increments 1.0 – 5.0 mA in 0.5 mA increments 5.0 – 20 mA in 1.0 mA increments
Ventricular	0.1 – 25 mA ± 0.1 mA or 10% (200-1000 Ohms)[b]	0.1 – 0.4 mA in 0.1 mA increments 0.4 – 1.0 mA in 0.2 mA increments 1.0 – 5.0 mA in 0.5 mA increments 5.0 – 25 mA in 1.0 mA increments
Pulse Width[c] (fixed)		
Atrial	1.0 ms ± 10%	
Ventricular	1.5 ms ± 10%	
Sensitivity[d]		
Atrial	ASYNC, 0.4 – 10 mV ± 0.3 mV or 25%	0.4 – 0.8 mV in 0.1 mV increments 0.8 – 2.0 mV in 0.2 mV increments 2.0 – 3.0 mV in 0.5 mV increments 3.0 – 10 mV in 1.0 mV increments
Ventricular	ASYNC, 0.8 – 20 mV ± 0.3 mV or 25%	0.8 – 1.0 mV in 0.2 mV increments 1.0 – 3.0 mV in 0.5 mV increments 3.0 – 10 mV in 1.0 mV increments 10 – 20 mV in 2.0 mV increments
A-V Interval		

Auto	50 – 250 ms ± 5 ms or 5% (PAV) ± 15 ms or 15% (SAV)	Paced A-V (PAV) = 300 – (1.67 x **RATE** in min^{-1}) Sensed A-V (SAV) = PAV – 30
Manual	20 – 300 ms ± 5 ms or 5%	in 10 ms increments
Refractory Period		
Atrial		
At atrial event	250 ms ± 10%	
At ventricular event (PVARP)	Auto (all values are ± 10%)	**Rate range** / **PVARP** ≤ 100 min^{-1} / 300 ms 105 – 150 min^{-1} / 250 ms 155 – 180 min^{-1} / 225 ms >180 min^{-1} / 200 ms
	Manual	150 – 500 ms ± 10% in 10 ms increments
Ventricular	250 ms ± 10%	
Upper Rate		
Auto	base rate + 30 min^{-1} ± 10%	minimum of 110 min^{-1}
Manual	80 – 230 min^{-1} ± 10%	80 – 130 min^{-1} in 2.0 min^{-1} increments 130 – 230 min^{-1} in 5.0 min^{-1} increments
Safety Pace	Occurs 110 ms after atrial pace, if A-V interval is set to more than 110 ms, or at programmed A-V interval if A-V interval is set to less than 110 ms	
Blanking[e]		
Atrial		
At atrial pace	DDD, DDI	A-V Interval
	AAI	125 ms + 50 ms/-0 ms
At atrial sense	DDD, DDI AAI	A-V Interval 75 ms + 50 ms/-0 ms
At atrial refractory sense	DDD, DDI, AAI	75 ms + 50 ms/-0 ms
At ventricular pace		125 ms + 50 ms/-0 ms
At ventricular sense		75 ms + 50 ms/-0 ms
Ventricular		
At atrial pace[f]		20 ms + 5 ms/-10 ms

At ventricular pace		125 ms + 50 ms/-0 ms
At ventricular sense		75 ms + 50 ms/-0 ms
Rate Limit	A crystal is used to set the pacing rate. If the crystal rate deviates from the appropriate value, the rate runaway protection circuit resets the device once. If the crystal rate remains incorrect, the rate runaway protection circuit turns the device off.	
Nominal Values		
Mode	DDD	DOO for Emergency
Rate	80 min^{-1}	
Output Amplitude		
Atrial	10 mA	20 mA for Emergency
Ventricular	10 mA	25 mA for Emergency
Pulse Width (fixed)		
Atrial	1.0 ms	
Ventricular	1.5 ms	
Sensitivity		
Atrial	0.5 mV	Asynchronous for Emergency
Ventricular	2.0 mV	Asynchronous for Emergency
AV Interval		
Sensed	140 ms	
Paced	170 ms	
PVARP	300 ms	
Upper Rate	110 min^{-1}	
Rapid Atrial Pacing Rate	320 min^{-1}	
Dimensions		
Height	21.1 cm (8.3 in.) ± 15%	
Width	8.1 cm (3.2 in.) ± 15%	
Depth (without dials)	3.6 cm (1.4 in.) ± 15%	
Weight (with battery)	510 g (18 oz.) maximum	
Temperature		
Operating	17°C to 33°C (64°F to 92°F)[g]	
Storage (without battery)	-40°C to 70°C (-40°F to 158°F)	

Battery Type	9 V Alkaline, type 6LR61, type 6F22E, NEDA 1604A (Eveready 522 or equivalent) 9 V Lithium, NEDA 1604LC (Ultralife U9VL or equivalent)
Battery Life	9 days typical, 7 days minimum (alkaline), or 16 days (lithium), when the rate is 70 min^{-1}, and all other parameters are at the nominal values listed above
Operation After Battery Removal	15 seconds (typical[h]) under the following conditions: **RATE** of 70 min^{-1} or less, **A OUTPUT** and **V OUTPUT** of 10 mA or less, backlight off, and lower screen blank.[i]

[a] An NBG code followed by "!?" indicates a clinically ineffective pacing mode.

[b] 20 - 25 mA ± 10% into 200 - 500 Ohms.

[c] Pulse width is measured at the 50% amplitude points of the leading and trailing edges, excluding the discharge cycle.

[d] When sensing 40 ms-wide Haversine waveform for ventricular inputs, 30 ms-wide Haversine waveform for atrial inputs.

[e] When tested with a 1 ms square pulse with sufficient amplitude.

[f] Ventricular blanking after an atrial pace is followed by 16 ms of reduced sensitivity. During this time the device detects R-waves with amplitudes of at least 5 mV or twice the **V SENSITIVITY** setting, whichever is greater.

[g] Within the ranges of 10°C to 17°C (50°F to 64°F) and 33°C to 43°C (92°F to 110°F) the specification for output is derated an additional ± 5%; the specification for sensitivity is derated an additional ± 7%; and the specification for rate is not derated.

[h] "Typical" is the average minimum value at 24 hours after the low battery indicator first appears.

[i] Medtronic does not recommend replacing the battery while the pacemaker is connected to a patient.

Device Accessories

Listed below are accessories for use with the Model 5388 Temporary Pacemaker. Contact your local Medtronic representative to obtain them.

- Model 5441 Disposable Cover
- Model 5409 Disposable Pouch

Model 5433 A/V Cable

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Special Notices

Special Notice for the Medtronic Model 5388 Temporary Pacemaker

Use of prior Medtronic Temporary Pacemakers has met with some success in the treatment of certain heart disorders, including heart block and heart arrhythmias. However Medtronic makes no warranty that the Model 5388 Temporary Pacemaker will efficiently restore adequate cardiac function for all patients. For information regarding common causes of pacing difficulty, consult other portions of the manual.

Special Notice for the Medtronic Model 5433A or Model 5433V Patient Cable

Cables may be easily damaged by improper handling or use due to their unavoidably fragile character, which is dictated by the unusual requirements of their application. Consequently, no representation or warranty is made that failure or cessation of function of cables will not occur.

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Definitions

Throughout this manual certain terms and symbols are used that are defined here for clarity.

The software program operating in the Model 5388 provides the pacemaker with the capabilities to respond to sensed signals in unique ways and to produce appropriate output signals. Some of the most frequently used terms to describe the software program activity of the Model 5388 are:

VSP — Ventricular Safety Pace. A stimulus to the ventricle to prevent inappropriate inhibition (see “Ventricular Safety Pacing” on page 50).

◆ — This small diamond is used to signify the end of the **UPPER RATE** interval.

* — A star indicates that the pacemaker has emitted an output pulse to that chamber.

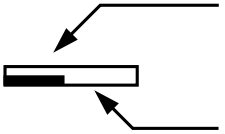
o — A circle indicates the pacemaker has sensed an event in that chamber.

ø A circle with a slash indicates an event sensed during a refractory or blanking period.

PVC Premature Ventricular Contraction. A ventricular sensed event following another ventricular sensed event without any intervening atrial paced or atrial sensed (inside or outside refractory) event.

A-V interval – A downward sloped line shows A-V timing initiated by an atrial output pulse or a sensed atrial event.

V-A interval – An upward sloped line shows the V-A interval initiated by a ventricular output pulse or a sensed ventricular event. This period, which is not directly programmable, has a value equal to the programmed base **RATE** interval minus the programmed PAV or SAV interval.



Blanking – A solid rectangle shows a blanking period, or absolute refractory period, during which the pacemaker is totally insensitive to signals.

Refractory – An open rectangle shows the refractory period. A refractory-sensed event does not affect the A-V or V-A interval, but restarts some blanking and refractory periods.

Reversion window – Period between the end of blanking and the end of refractory. Reversion occurs when the device senses repeatedly in successive reversion windows, then paces asynchronously.

Blanking and Refractory Periods

Blanking Periods

PAAB Period – The Post Atrial Atrial Blanking period prevents the atrial sense amplifier from sensing the atrial pace pulse.

PAVB Period – The Post Atrial Ventricular Blanking period prevents the ventricular sense amplifier from sensing an atrial pulse (crosstalk).

PVAB Period – The Post Ventricular Atrial Blanking period prevents the atrial sense amplifier from sensing a ventricular pulse (crosstalk).

PVVB Period – The Post Ventricular Ventricular Blanking period prevents the ventricular sense amplifier from sensing a ventricular pace pulse.

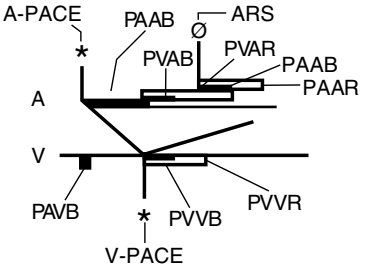


Figure A-1. Typical Blanking and Refractory Periods.

Refractory Periods

PVARP – The Post Ventricular Atrial Refractory Period prevents atrial sensing of crosstalk (far-field R-wave, retrograde conducted R-wave), which may trigger PMT (pacemaker-mediated tachycardia). **PVARP** also provides a reversion window.

PVVR Period – The Post Ventricular Ventricular Refractory period provides a reversion window.

PAAR Period – The Post Atrial Atrial Refractory period is started only when an atrial event is sensed inside **PVARP**.

The two A-V intervals are:

PAV Interval – Pace A-V interval (**A-V INTERVAL**) is the A-V interval after an atrial pace. It is programmable.

SAV Interval – Sense A-V interval is the A-V interval after an atrial sense. This parameter is not programmable and is set to PAV minus 30 ms.

Single Chamber Modes

The Model 5388 will pace in four single chamber modes: AOO, VOO, AAI, and VVI.

AOO and VOO Modes

The asynchronous modes (AOO and VOO) emit a pacing pulse into one chamber, either the atrium (AOO) or the ventricle (VOO), at the end of the base rate interval, regardless of any intrinsic activity.

When pacing in the AOO mode, the pacemaker will pace the atrium asynchronously at the programmed base **RATE**. The atrial and ventricular channels are continuously blanked.

When pacing in the VOO mode, the pacemaker will pace the ventricle asynchronously at the programmed base **RATE**. The atrial and ventricular channels are continuously blanked.

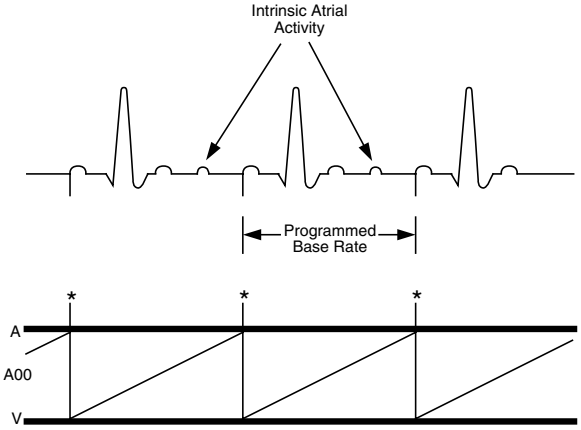
AAI and VVI Modes

In the inhibited (or demand) modes (AAI and VVI), when an intrinsic beat is sensed outside of a refractory period, and before timeout of the base rate interval, the pacemaker inhibits the output pulse. If no intrinsic beat is sensed before the timeout of the base rate, a pacing stimulus is delivered.

When pacing in the AAI mode, the pacemaker will pace the atrium at the programmed base **RATE** in the absence of detected atrial activity. The ventricular channel is continuously blanked.

When pacing in the VVI mode, the pacemaker will pace the ventricle at the programmed base **RATE** in the absence of detected ventricular activity. The atrial channel is continuously blanked.

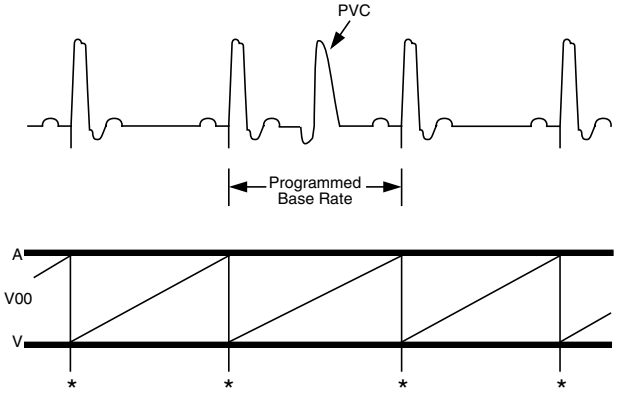
AOO



When the base **RATE** interval times out, the pacemaker will:

- Restart the base **RATE** interval, and
- Deliver a pacing stimulus to the atrium.

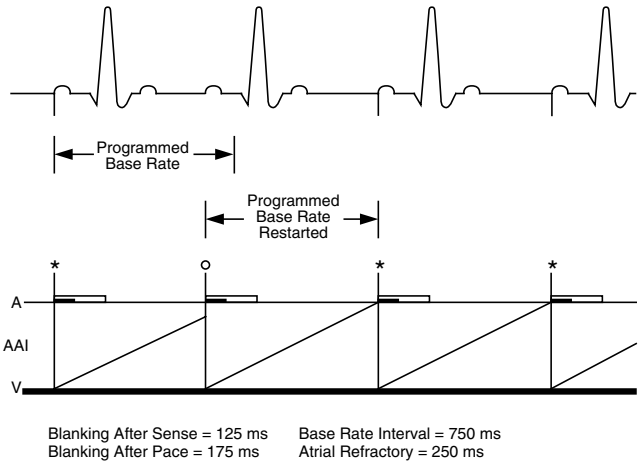
VOO



When the base **RATE** interval times out, the pacemaker will:

- Restart the base **RATE** interval, and
- Deliver a pacing stimulus to the ventricle.

AAI

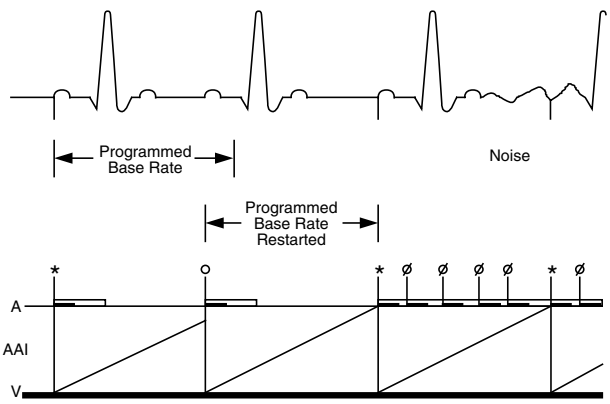


Blanking After Sense = 125 ms
Blanking After Pace = 175 ms
Base Rate Interval = 750 ms
Atrial Refractory = 250 ms

If the base **RATE** interval times out, the pacemaker will:

- Restart the base **RATE** interval,
- Start the atrial refractory and blanking (after pace) periods, and
- Deliver a pacing stimulus in the atrium.

AAI



Blanking After Sense = 125 ms
Blanking After Pace = 175 ms
Base Rate Interval = 750 ms
Atrial Refractory = 250 ms

If a detected atrial event occurs outside of the atrial refractory period, the pacemaker will:

- Restart the base **RATE** interval, and
- Start the atrial refractory and blanking (after sense) periods.

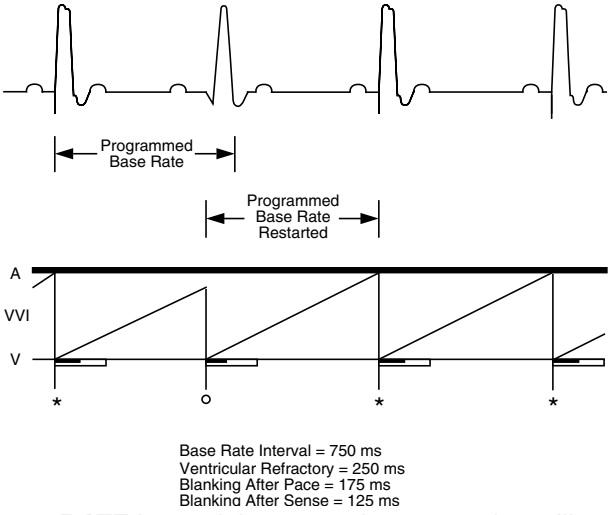
If a detected atrial event occurs within the atrial refractory period, the pacemaker will:

- Not restart the base **RATE** interval,
- Restart the atrial refractory and blanking (after sense) periods.

Note: This action forces asynchronous atrial pacing in the presence of continuous noise (reversion behavior).

If the atrial event occurs within the atrial blanking period, it is not sensed, and no action is taken.

VVI

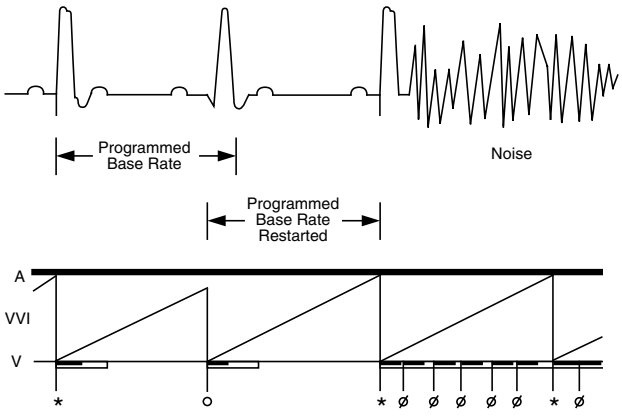


Base Rate Interval = 750 ms
Ventricular Refractory = 250 ms
Blanking After Pace = 175 ms
Blanking After Sense = 125 ms

If the base **RATE** interval times out, the pacemaker will:

- Restart the base **RATE** interval,
- Start the ventricular refractory and blanking (after pace) periods, and
- Deliver a pacing stimulus in the ventricle.

VVI



Base Rate Interval = 750 ms
Ventricular Refractory = 250 ms
Blanking After Pace = 175 ms
Blanking After Sense = 125 ms

If a detected ventricular event occurs outside of the ventricular refractory period, the pacemaker will:

- Restart the base **RATE** interval, and
- Start the ventricular refractory and blanking (after sense) periods.

If a detected ventricular event occurs within the ventricular refractory period the pacemaker will:

- **Not** restart the base **RATE** interval, but
- Restart the ventricular refractory and blanking (after sense) periods.

Note: This action forces asynchronous ventricular pacing in the presence of continuous noise (reversion behavior).

If the ventricular event occurs within the ventricular blanking period, it is not sensed, and no action is taken.

Dual Chamber Modes

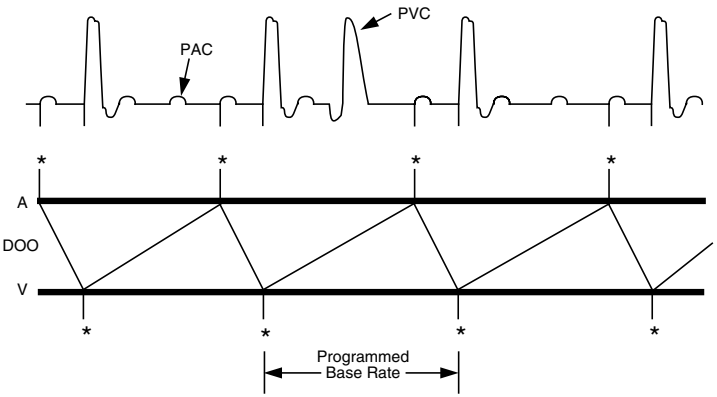
The Model 5388 will pace in four dual-chamber modes: DOO, DVI, DDD, and DDI.

Note: Modes that are punctuated by “!?” on the Menu screens should be avoided or adjusted to a clinically useful mode.

DOO Mode

When pacing in the A-V sequential asynchronous mode (DOO), the pacemaker will pace the atrium and the ventricle asynchronously at the programmed base **RATE** and with the programmed **A-V INTERVAL**. Both channels are continuously blanked.

DOO



When the V-A interval times out, the pacemaker will:

- Start the **A-V INTERVAL**, and
- Deliver a pacing stimulus in the atrium.

When the **A-V INTERVAL** times out, the pacemaker will:

- Start the V-A interval, and
- Deliver a pacing stimulus in the ventricle.

DVI Mode

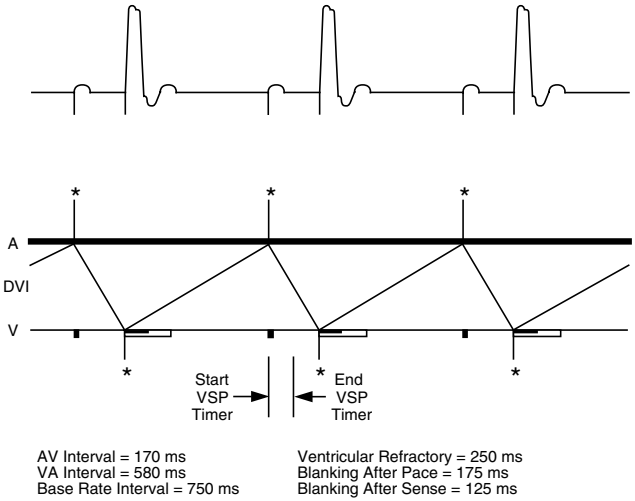
In the ventricular demand A-V sequential (DVI) mode there is no atrial sensing function. If a ventricular event is sensed outside of a refractory period during the V-A interval, the pacemaker restarts the V-A interval. If a ventricular event is sensed during the programmed **A-V INTERVAL**, the pacemaker inhibits the ventricular stimulus and starts the V-A interval. The exception to this is safety pacing, which is described later.

This mode is normally used when A-V synchrony is desired but the atrium is prone to arrhythmias.

Notes:

- **PVARP** and **UPPER RATE** do not apply in this mode.
- When pacing in the DVI mode, the pacemaker will pace the atrium and the ventricle at the programmed base **RATE** and with the programmed **A-V INTERVAL** in the absence of detected ventricular electrical activity. The atrial sense amplifier is continuously blanked.

DVI



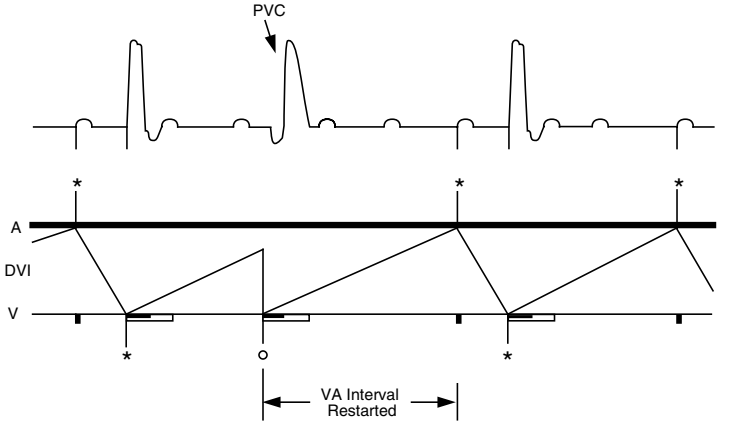
If the V-A interval times out, the pacemaker will:

- Start the ventricular safety pace timer (VSP),
- Start the **A-V INTERVAL**,
- Start the PAVB period, and
- Deliver a pacing stimulus in the atrium.

If no ventricular event is sensed and the **A-V INTERVAL** times out, the pacemaker will:

- Start the V-A interval,
- Start the PVVR and PVVB (after pace) periods, and
- Deliver a pacing stimulus in the ventricle.

DVI



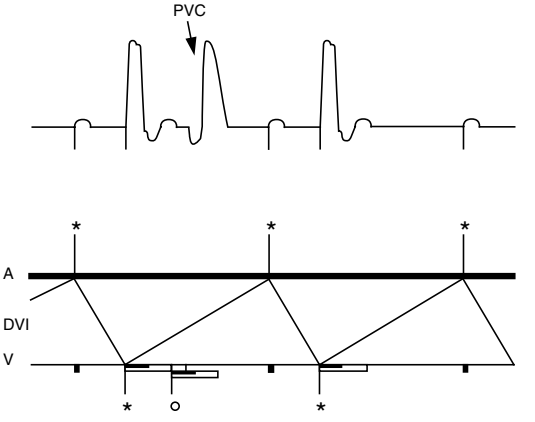
AV Interval = 170 ms
VA Interval = 580 ms
Base Rate Interval = 750 ms

Ventricular Refractory = 250 ms
Blanking After Pace = 175 ms
Blanking After Sense = 125 ms

If the detected ventricular event occurs outside of the ventricular refractory period and in the V-A interval, the pacemaker will:

- Restart the V-A interval, and
- Start the PVVR and PVVB (after sense) periods.

DVI



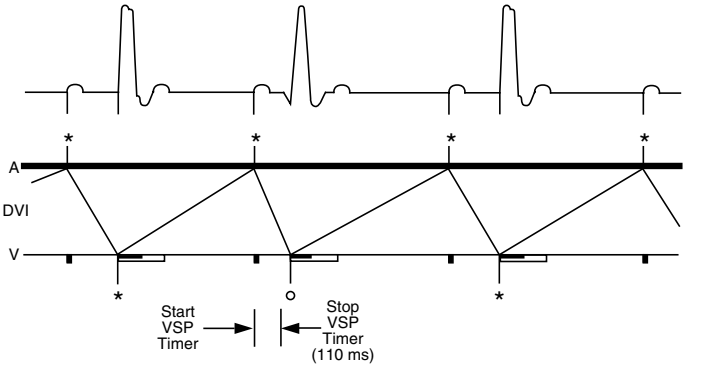
AV Interval = 170 ms
VA Interval = 580 ms
Base Rate Interval = 750 v

Ventricular Refractory = 250 ms
Blanking After Pace = 175 ms
Blanking After Sense = 125 ms

If the ventricular event is sensed inside the ventricular refractory period, and in the V-A interval, the pacemaker will:

- **Not** restart the V-A interval
- Start the PVVR and PVVB (after sense) periods.

DVI



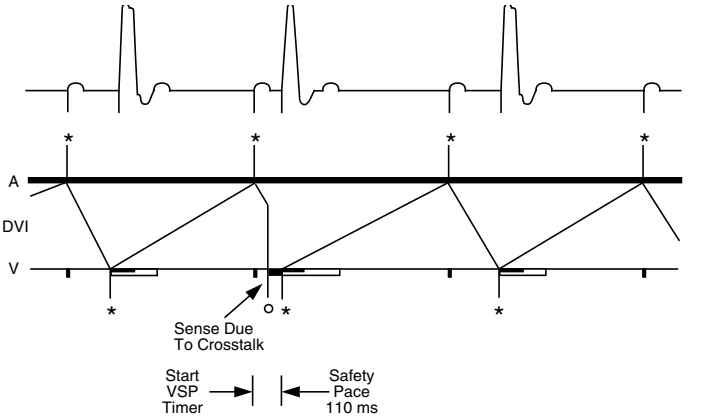
AV Interval = 170 ms
VA Interval = 580 ms
Base Rate Interval = 750 ms

Ventricular Refractory = 250 ms
Blanking After Pace = 175 ms
Blanking After Sense = 125 ms

If the ventricular event is sensed outside the ventricular safety pace window, and in the **A-V INTERVAL**, the pacemaker will:

- Start the V-A interval, and
- Start the PVVR and PVVB (after sense) periods.

DVI



AV Interval = 170 ms
VA Interval = 580 ms
Base Rate Interval = 750 ms
Ventricular Refractory = 250 ms
Blanking After Pace = 175 ms
Blanking After Sense = 125 ms

If the **A-V INTERVAL** is programmed to more than 110 ms, then when a ventricular sensed event occurs inside the ventricular safety pace window, the pacemaker will:

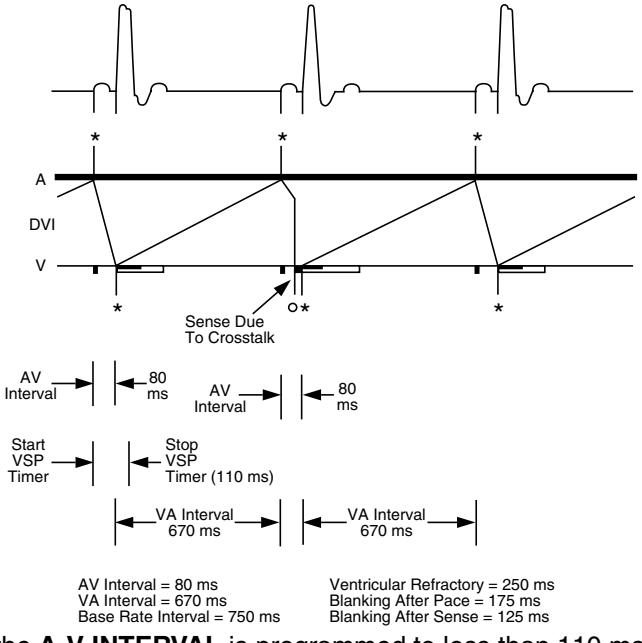
- Start PVVR and PVVB (after sense), and
- Schedule a safety pacing stimulus in the ventricle 110 ms after the atrial event.

After the 110 ms period, the pacemaker will:

- Start the V-A interval,
- Restart PVVR and PVVB (after pace), and
- Deliver a pacing stimulus in the ventricle.

Note: The response is similar if the ventricular-sensed event is a refractory sense inside the ventricular safety pace window.

DVI



AV Interval = 80 ms
VA Interval = 670 ms
Base Rate Interval = 750 ms
Ventricular Refractory = 250 ms
Blanking After Pace = 175 ms
Blanking After Sense = 125 ms

If the **A-V INTERVAL** is programmed to less than 110 ms, then when
a ventricular sensed event occurs inside the ventricular safety pace window, the pacemaker will:

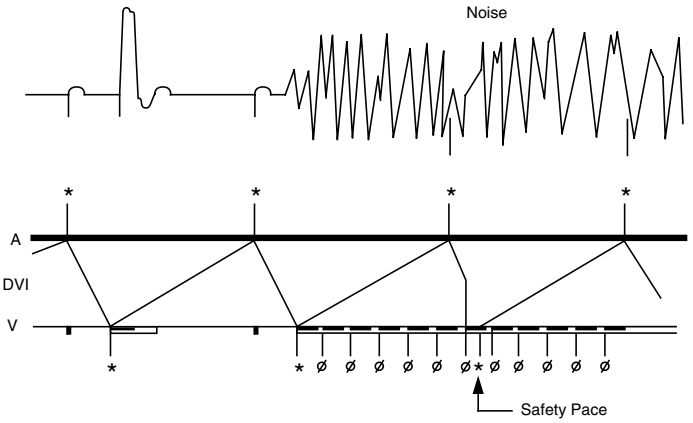
- Start the PVVR and PVVB (after sense) periods.

At the end of **A-V INTERVAL**, the pacemaker will:

- Deliver a pacing stimulus in the ventricle,
- Start the V-A interval, and
- Restart PVVR and PVVB (after pace).

Note: The response is similar if the ventricular-sensed event is a refractory sense inside the ventricular safety pace window.

DVI



AV Interval = 170 ms
VA Interval = 580 ms
Base Rate Interval = 750 ms

Ventricular Refractory = 250 ms
Ventricular Blanking After Pace = 175 ms
Ventricular Blanking After Sense = 125 ms

If the detected events occur within successive ventricular refractory periods, the pacemaker will:

- Restart the PVVR and PVVB (after sense) periods, and
- Not restart the V-A interval.
- Asynchronously pace in both chambers.
  - The rate is equal to the V-A interval plus 110 ms if the **A-V INTERVAL** is set longer than the ventricular safety window (110 ms). The rate will be shorter than the programmed base **RATE**.
  - The rate is equal to the programmed base **RATE** if the **A-V INTERVAL** is set shorter than 110 ms.

  The pacemaker is essentially in DOO mode.

DDD Mode

This mode provides a P-wave synchronous rate response with A-V sequential pacing. Intrinsic activity in the atrium and ventricle inhibits output stimuli and restarts certain timers.

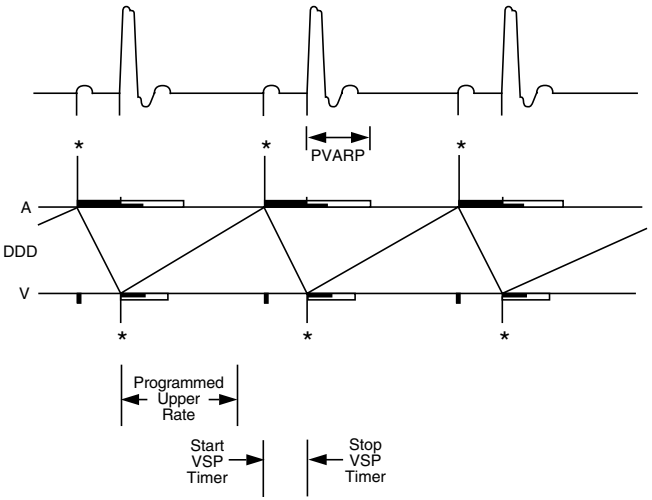
Without atrial events within certain periods, the pacemaker delivers a pacing stimulus to the atrium at the end of the V-A interval which is equal to the programmed base **RATE** minus the programmed **A-V INTERVAL**.

Without ventricular activity during certain periods, the pacemaker delivers a pacing stimulus to the ventricle at the end of the programmed **A-V INTERVAL**. An exception to this is safety pacing, which is illustrated in the diagrams.

The pacing rate can be limited by the programmed **UPPER RATE** so that the pacemaker does not pace the ventricle too fast in the presence of atrial arrhythmias.

When pacing in the DDD mode, the pacemaker will pace the atrium and the ventricle at the programmed base **RATE** and with the programmed **A-V INTERVAL** in the absence of detected atrial or ventricular intrinsic events.

DDD



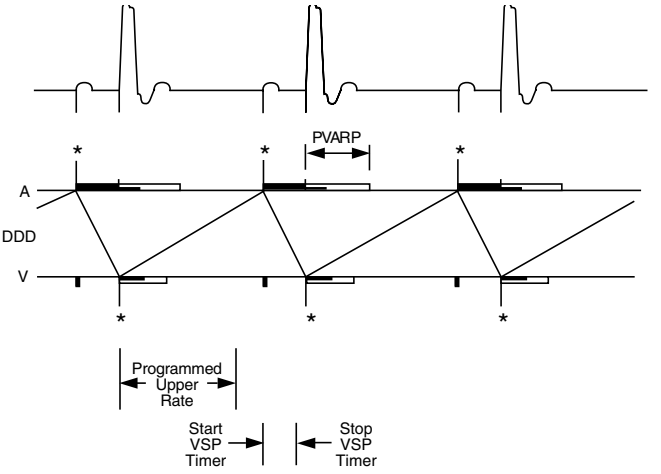
AV Interval = 170 ms
VA Interval = 580 ms
Base Rate Interval = 750 ms
Upper Rate Interval = 545 ms

PVARP = 300 ms
Ventricular Refractory = 250 ms
Blanking After Pace = 175 ms
Blanking After Sense = 125 ms

If the V-A interval times out, the pacemaker will:

- Start the ventricular safety pace timer,
- Start the PAAB period, which is set to the same value as the **A-V INTERVAL**,
- Start the PAVB period,
- Start the **A-V INTERVAL**, and
- Deliver a pacing stimulus in the atrium.

DDD



AV Interval = 170 ms
VA Interval = 580 ms
Base Rate Interval = 750 ms
Upper Rate Interval = 545 ms

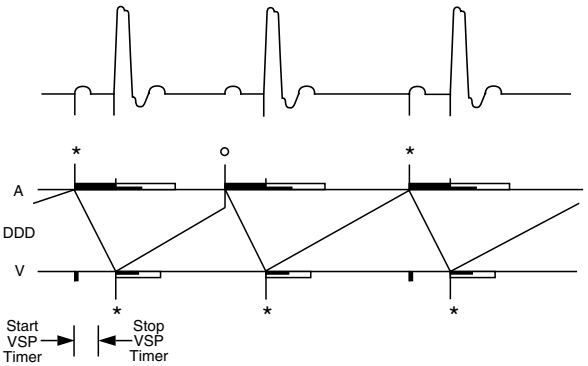
PVARP = 300 ms
Ventricular Refractory = 250 ms
Blanking After Pace = 175 ms
Blanking After Sense = 125 ms

If no ventricular event is sensed, and the **A-V INTERVAL** times out, and the **UPPER RATE** interval has timed out, the pacemaker will:

- Start the PVAB (after pace) period and **PVARP**,
- Start the PVVB (after pace) and PVVR periods,
- Start the **UPPER RATE** interval,
- Start the V-A interval, and
- Deliver a pacing stimulus in the ventricle.

Note: UPPER RATE is started by a ventricular pace, a ventricular sense or a ventricular refractory sense. **UPPER RATE** is effective only after an atrial sense (not an atrial refractory sense).

DDD



SAV Interval = 170 ms – 30 ms = 140 ms
VA Interval = 580 ms
Base Rate Interval = 750 ms
Upper Rate Interval = 545 ms

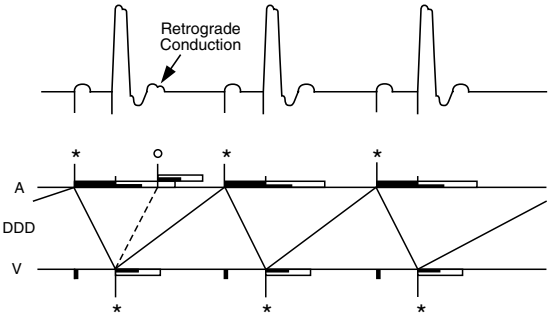
PVARP = 300 ms
Ventricular Refractory = 250 ms
Blanking After Pace = 175 ms
Blanking After Sense = 125 ms

If the detected atrial event occurs outside of the **PVARP**, the pacemaker will:

- Start the PAAB period, which is set to the same value as the SAV interval, and
- Start the SAV interval.

Note: There is no PAVB period initiated upon an atrial sensed event since a sensed event (as compared to a paced event) is assumed to be small in amplitude and to not result in crosstalk. An atrial sensed event also does not start the ventricular safety pace timer.

DDD



SAV Interval = 170 ms – 30 ms = 140 ms
VA Interval = 580 ms
Base Rate Interval = 750 ms
Upper Rate Interval = 545 ms

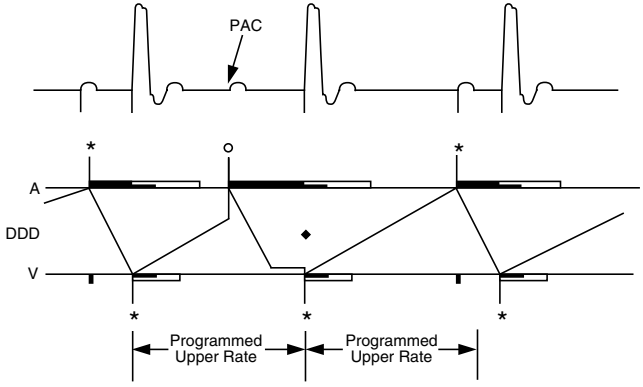
PVARP = 300 ms
Ventricular Refractory = 250 ms
Blanking After Pace = 175 ms
Blanking After Sense = 125 ms

If the atrial event occurs inside the **PVARP** (a PAC, a far-field ventricular event, a retrograde conducted ventricular event) the pacemaker will:

- Restart PAAR and PAAB (after sense) periods, and
- **Not** start SAV interval.

Note: This action prevents pacemaker-mediated tachycardia (PMT).

DDD



SAV Interval = 170 ms – 30 ms = 140 ms
VA Interval = 580 ms
Base Rate Interval = 750 ms
Upper Rate Interval = 545 ms

PVARP = 300 ms
Ventricular Refractory = 250 ms
Blanking After Pace = 175 ms
Blanking After Sense = 125 ms

◆ = End of Upper Rate Interval

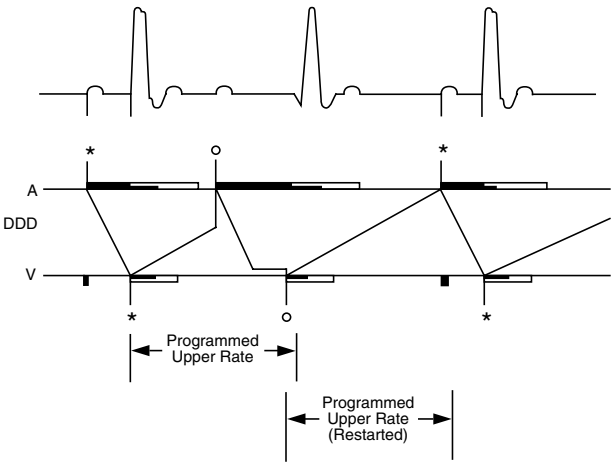
If no ventricular event is sensed and the SAV interval times out from a preceding atrial sensed event and the **UPPER RATE** interval has not timed out, the pacemaker will:

- Extend PAAB, and
- Schedule a pacing stimulus in the ventricle when the **UPPER RATE** interval times out.

Then, if no ventricular event is sensed and the **UPPER RATE** interval times out, the pacemaker will:

- Start the **PVARP** and PVAB (after pace) period,
- Start the PVVR and PVVB (after pace) periods,
- Restart the **UPPER RATE** interval,
- Start the V-A interval, and
- Deliver a pacing stimulus in the ventricle.

DDD



SAV Interval = 170 ms – 30 ms = 140 ms
VA Interval = 580 ms
Base Rate Interval = 750 ms
Upper Rate Interval = 545 ms

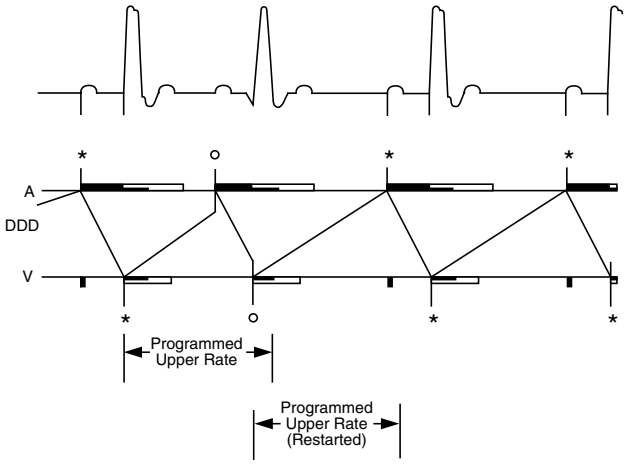
PVARP = 300 ms
Ventricular Refractory = 250 ms
Blanking After Pace = 175 ms
Blanking After Sense = 125 ms

If a ventricular sensed event occurs outside of the ventricular refractory and the SAV interval has timed out and the **UPPER RATE** interval has not timed out and a ventricular pace has been scheduled, the pacemaker will:

- Start the **PVARP** and PVAB (after sense) period,
- Start the PVVR and PVVB (after sense) periods,

- Restart the **UPPER RATE** interval,
- Start the V-A interval, and
- Cancel the scheduled ventricular pace.

DDD



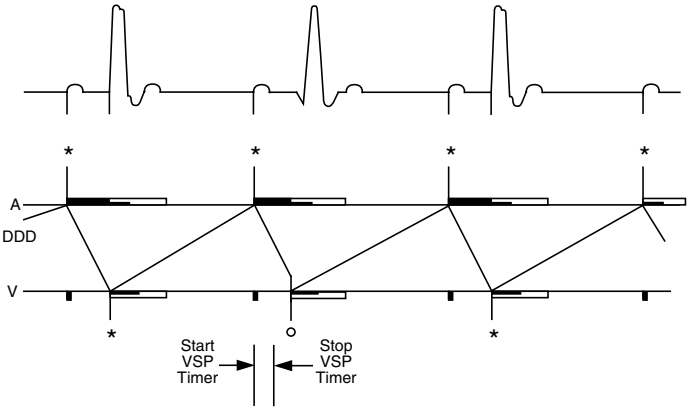
SAV Interval = 170 ms – 30 ms = 140 ms
VA Interval = 580 ms
Base Rate Interval = 750 ms
Upper Rate Interval = 545 ms

PVARP = 300 ms
Ventricular Refractory = 250 ms
Blanking After Pace = 175 ms
Blanking After Sense = 125 ms

If a ventricular sensed event occurs outside of the ventricular refractory and the SAV interval has not timed out and the **UPPER RATE** interval has not timed out, the pacemaker will:

- Start the **PVARP** and PVAB (after sense) period,
- Start the PVVR and PVVB (after sense) periods,
- Restart the **UPPER RATE** interval,
- Start the V-A interval, and
- Cancel the scheduled ventricular pace.

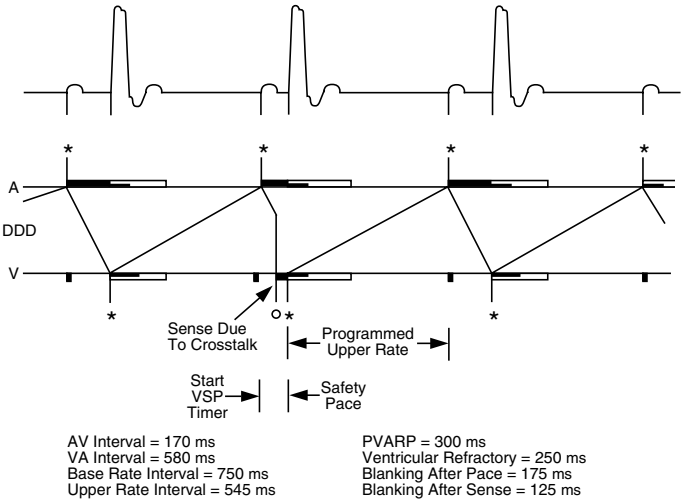
DDD



If the detected ventricular event occurs outside of the ventricular refractory period and the ventricular safety pace timer has timed out and the **A-V INTERVAL** timer has not timed out, the pacemaker will:

- Start the **PVARP** and PVAB (after sense) period,
- Start the PVVR and PVVB (after sense) period,
- Start the **UPPER RATE** interval,
- Start the V-A interval, and
- Cancel the scheduled ventricular pace.

DDD



If the **A-V INTERVAL** is programmed to more than 110 ms and a ventricular event is sensed before the VSP timer times out, the pacemaker will:

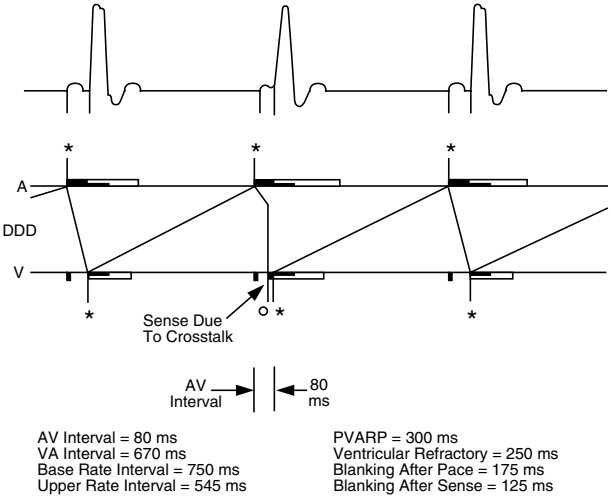
- Start the PVVB (after sense) period,
- Continue the PVAB (after sense) period, and
- Schedule a safety pacing stimulus in the ventricle 110 ms after the atrial event.

Then when the ventricular safety pace period times out 110 ms later, the pacemaker will:

- Start the **PVARP** and PVAB (after pace) period,
- Start the PVVR and PVVB (after pace) periods,
- Start the **UPPER RATE** interval,
- Start the V-A interval, and
- Deliver a pacing stimulus in the ventricle.

Note: The response is similar if the ventricular-sensed event is a refractory sense inside the ventricular safety pace window.

DDD



When the **A-V INTERVAL** is programmed to less than 110 ms and when a detected ventricular event occurs and the **A-V INTERVAL** has not timed out, the pacemaker will:

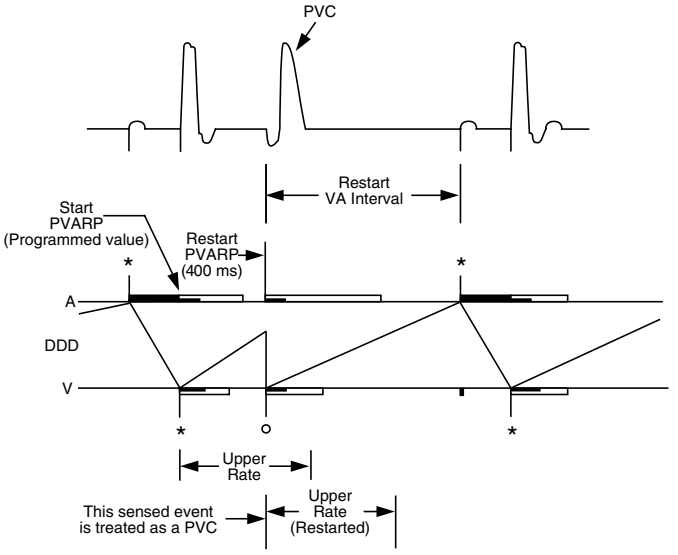
- Start the PVVB (after sense) period,
- Continue the PVAB (after sense) period, and
- Schedule a pacing stimulus in the ventricle at the end of **A-V INTERVAL**.

Then when the **A-V INTERVAL** does time out, the pacemaker will:

- Start the PVVR and PVVB (after pace) period,
- Start the **PVARP** and PVAB (after pace) period,
- Start the **UPPER RATE** interval,
- Start the V-A interval, and
- Deliver a pacing stimulus to the ventricle.

Note: The response is similar if the ventricular-sensed event is a refractory sense inside the ventricular safety pace window.

DDD



AV Interval = 170 ms
VA Interval = 580 ms
Base Rate Interval = 750 ms
Upper Rate Interval = 545 ms

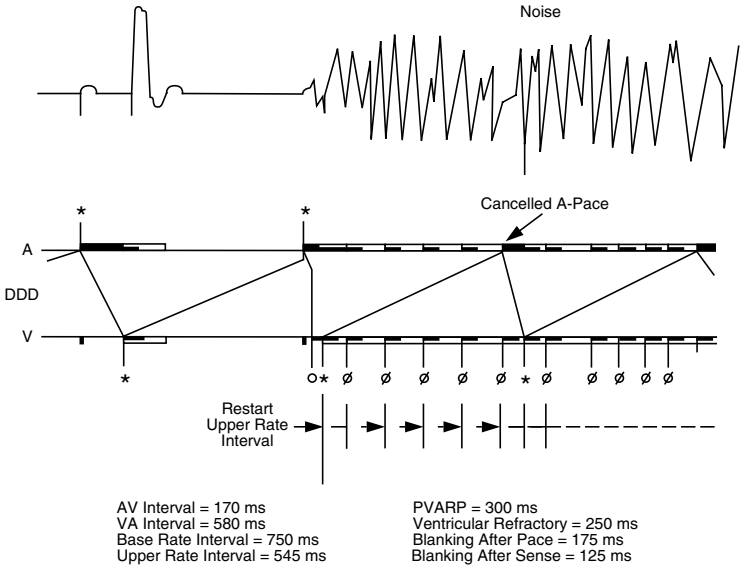
PVARP = 300 ms
Ventricular Refractory = 250 ms
Blanking After Pace = 175 ms
Blanking After Sense = 125 ms

If the detected ventricular event occurs outside of the ventricular refractory period, and the V-A interval has not timed out, and the event is recognized as a PVC, the pacemaker will:

- Start the **PVARP** at a value of 400 ms, or to the programmed value if set longer than 400 ms, because the event is recognized as a PVC,
- Start the PVAB (after sense) period,
- Start the PVVR and PVVB (after sense) periods,
- Restart the **UPPER RATE** interval, and
- Restart the V-A interval.

Note: PVARP is extended only during the cycle in which the PVC is recognized. Otherwise it goes back to the programmed value.

DDD



If ventricular events are sensed in successive ventricular refractory periods, the pacemaker will:

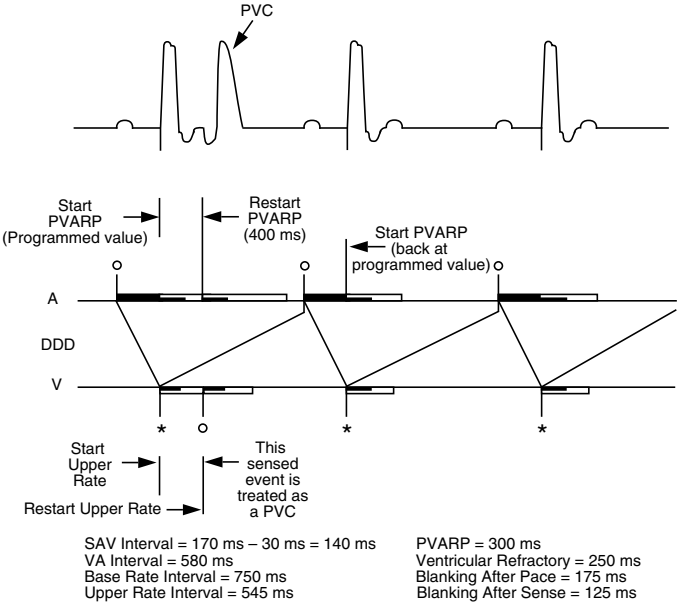
- Inhibit atrial pacing and sensing, and
- Asynchronously pace in the ventricle at the programmed base **RATE**.

  The pacemaker is essentially in VOO mode.

Notes:

- A cancelled atrial pace will **not** start a ventricular safety pace window.
- **UPPER RATE** does not delay a ventricular pace after a cancelled atrial pace.
- **PVARP**, as well as ventricular refractory, is continuously restarted by ventricular refractory sensed events.

DDD

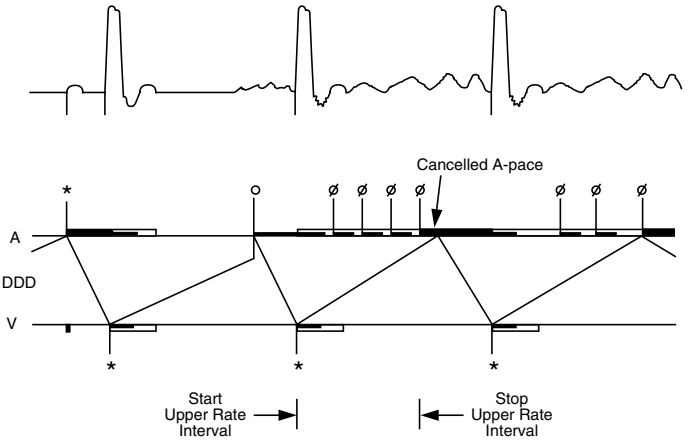

PVC
Start PVARP (Programmed value)
Restart PVARP (400 ms)
Start PVARP (back at programmed value)
A
DDD
V
Start Upper Rate
Restart Upper Rate
This sensed event is treated as a PVC
SAV Interval = 170 ms – 30 ms = 140 ms
VA Interval = 580 ms
Base Rate Interval = 750 ms
Upper Rate Interval = 545 ms
PVARP = 300 ms
Ventricular Refractory = 250 ms
Blanking After Pace = 175 ms
Blanking After Sense = 125 ms

If the detected ventricular event occurs within the ventricular refractory period (outside of blanking) and the V-A interval has not timed out, and the event is recognized as a PVC, the pacemaker will:

- Restart the **PVARP**, at a value of 400 ms, or to the programmed **PVARP** if set longer than 400 ms, because the event is recognized as a PVC,
- Restart the PVAB (after sense) period,
- Restart the PVVR and PVVB (after sense) periods,
- Restart the **UPPER RATE** interval, but
- **Not** restart the V-A interval.

Note: PVARP is extended only during the cycle in which the PVC is recognized. Otherwise it goes back to the programmed value.

DDD



AV Interval = 170 ms	PVARP = 300 ms
VA Interval = 580 ms	Ventricular Refractory = 250 ms
Base Rate Interval = 750 ms	Blanking After Pace = 175 ms
Upper Rate Interval = 545 ms	Blanking After Sense = 125 ms

If atrial events are sensed in successive atrial refractory periods (atrial tachycardia with a cycle time of about 100 to 250 ms), the pacemaker will:

- Cancel the scheduled atrial pacing stimulus at the end of the V-A interval to prevent pacing into an atrial tachycardia and potentially converting it into atrial fibrillation, and
- Pace in the ventricle in the demand mode at the programmed base **RATE**.

Note: Since the atrial pacing stimulus is inhibited, the atrial pace indicator will not be lit. The atrial sense indicator will light each time there is an atrial event sensed inside or outside the refractory period.

The pacemaker is essentially in VVI mode.

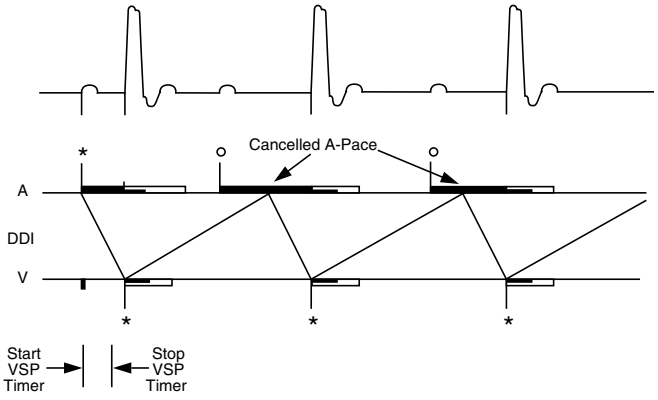
Note: A cancelled atrial pace will not start a ventricular safety pace window.

DDI Mode

The device behaves in DDI mode as in DDD mode in all aspects except the following: the pacing in the ventricle does not track atrial sensed events. This mode is used when physiological pacing is desired, but the patient is prone to atrial arrhythmia.

Note: In DDI mode, **UPPER RATE** is not applicable.

DDI



If the non-refractory atrial event is detected in the V-A interval, the pacemaker will:

- Start the PAAB (after sense) period, which starts with the atrial sensed event and continues until the delivery of the ventricular pace, and
- **Not** start the SAV interval.

At the end of V-A interval, the pacemaker will:

- Cancel the scheduled atrial pacing stimulus, and
- Start the **A-V INTERVAL**.

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